UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

In re Mylan N.V. Securities Litigation

Case No. 1:16-CV-07926 (JPO)

SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF SECURITIES LAWS

JURY TRIAL DEMANDED

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Lead Plaintiffs Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd. and Dan Kleinerman ("Plaintiffs" or "Lead Plaintiffs") on behalf of a class of all purchasers of Mylan N.V. common stock in the United States (the "Class"), allege the following by and through their attorneys and on behalf of all other persons and entities similarly situated. All of the following allegations are made upon information and belief, except those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Mylan N.V. ("Mylan" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Mylan; (c) review of complaints filed in other actions against Mylan and its executives; (d) review of other publicly available information concerning Mylan; and (e) interviews with former employees of Mylan.

I. INTRODUCTION

- 1. This is a class action (the "Action") on behalf of a class of persons or entities that acquired the securities of Mylan N.V. and/or Mylan N.V.'s predecessor, Mylan Inc., between February 21, 2012 and October 30, 2017, both dates inclusive (the "Class Period"). The Action seeks to recover damages and to obtain other remedies for Defendants' violations of the Securities Exchange Act of 1934 (the "Exchange Act").
- 2. Mylan, together with its subsidiaries, develops, licenses, manufactures, markets, and distributes brand-name and generic pharmaceuticals worldwide. Mylan manufactures and sells, among other products, the EpiPen Auto-Injector® and EpiPen Jr Auto-Injector® (collectively, the "EpiPen"), a branded drug that allows the user to autoinject a measured dose

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of epinephrine to treat anaphylaxis, a life-threatening emergency to which one in thirteen children is susceptible. Mylan also manufactures and sells the following generic drugs, among others: albuterol sulfate, used to treat asthma and other lung conditions; benazepril, used to treat high blood pressure; clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness; divalproex, used to treat certain types of seizures and migraines; doxycycline hyclate delayed release ("Doxy DR"), a tetracycline antibiotic used to treat a wide range of bacterial infections, including severe respiratory infections and anthrax; and propranolol, a beta-blocker used to treat and prevent heart attack and other heart and circulatory conditions.

- 3. Mylan is a dishonest company. Over the past two decades, in over a dozen matters, Mylan has repeatedly been investigated by the FTC, the DOJ and the SEC, and sued by private litigants, for fraudulently overcharging Medicaid for its drug purchases, for illegal price manipulation, for entering into illegal anticompetitive agreements, and for other wrongful conduct. These wrongs by Mylan are chronic—Mylan has repeated the same misdeeds time and again. And while the wrongs addressed in this Action are only the most recent examples of Mylan's proven history of such misdeeds, they are perhaps the most serious. Through the conduct described in this complaint, Mylan made lifesaving drugs less available to children, the elderly, and other ordinary Americans who struggle to afford these drugs.
- 4. Plaintiffs bring this Action because, during the Class Period, Mylan misled Plaintiffs about a course of conduct intended to cheat Medicaid (the U.S. low-income healthcare program) out of its rightful rebates for EpiPen purchases, about anticompetitive conduct to exclude competition that allowed it to inflate the price of EpiPen astronomically, beyond the reach of many consumers, and about a scheme to inflate the prices of critical generic drugs by

over 1000% by engaging in numerous anticompetitive activities. In particular: (1) Mylan systematically and knowingly misclassified the EpiPen as a generic drug in order to overcharge Medicaid by hundreds of millions of dollars for its purchases of this life-saving device for Medicaid recipients; (2) Mylan entered into exclusive dealing arrangements with commercial insurance companies and pharmaceutical benefit managers in order to prevent competitor Sanofi-Aventis from successfully introducing a product to compete with EpiPen; and (3) Mylan entered into, and maintained, anticompetitive agreements with its "competitors" to allocate the market for Doxy DR, and to fix the prices of generic albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, doxycycline monohydrate, glipizide-metformin and verapamil at stratospheric levels.

- 5. First, as soon as Mylan acquired the rights to market the EpiPen, Mylan knowingly misclassified the EpiPen for the purposes of the Medicaid Drug Rebate Program ("MDRP"). Under the MDRP, drug companies enter a contract with the agency that administers Medicaid, the Centers for Medicare & Medicaid Services ("CMS"), under which they agree to give CMS rebates on their drugs—rebates that represent bulk discounts on CMS's massive drug purchases for Medicaid. Federal law requires companies to give Medicaid a lower rebate for generic drugs, which drug companies already sell at close to cost, than for brand name or patented drugs, which drug companies usually sell at a significant markup. The responsibility of categorizing drugs correctly as generic or brand name drugs lies with the drug companies.
- 6. This categorization is remarkably straightforward, and follows unambiguously from laws and regulations that have remained essentially unchanged since 1990, when the MDRP was first implemented—if the FDA approved a drug under a new drug application

("NDA") (which is used for new, usually patented drugs), that drug is a brand name drug for the purposes of the MDRP, and if the drug was not approved under an NDA, the drug is a generic drug.

- There is not, and never has been, any question about how the EpiPen should be classified. Even a layperson wholly unfamiliar with laws and regulations regarding classification of the EpiPen would know that the EpiPen is a brand-name drug and not a generic—it is an extremely expensive, branded and patented product that bears a trademarked logo rather than an active ingredient on its label—it is nothing like the cheap generic medication Congress expected already to be sold at close to cost. But just as importantly, a layperson also would have no trouble classifying the drug under Medicaid's laws and regulations—all he or she would need to do would be to look up the EpiPen on the FDA's website and note that it was approved under an NDA in order to classify the drug as a brand name drug for the purposes of the MDRP. No exceptions to this rule existed in the laws and regulations governing classification of drugs for the purposes of the MDRP.
- 8. Mylan is not a layperson; rather, Mylan has an army of highly sophisticated lawyers. These lawyers were capable of doing what a layperson could do—of classifying the EpiPen correctly as a brand-name drug. Instead, Mylan knowingly misclassified the EpiPen as a generic, from when it first acquired rights to the drug in 2007 to the present.
- 9. Indeed, before the Class Period, CMS expressly notified Mylan that the EpiPen was misclassified, as the Acting Administrator Andrew M. Slavitt has confirmed in correspondence with the U.S. Senate. In early 2009, the Inspector General of the Department of Health and Human Services expressly told CMS that the EpiPen was misclassified for the purposes of the MDRP. Thereafter, on multiple occasions CMS expressly notified Mylan that

the EpiPen was misclassified. As Slavitt stated in an October 5, 2016 letter to Senator Ron Wyden, "CMS has, on multiple occasions . . . expressly told Mylan that the product [EpiPen] is incorrectly classified." As detailed below, the most reasonable inference to be drawn about the timing of this notification is that CMS was not completely derelict in its duties and notified Mylan of this misclassification within three years at the latest upon receiving notice from the Inspector General.

- 10. Mylan repeatedly misrepresented to investors the legal situation it faced as a result of its blatant misclassification of the EpiPen for the purposes of the MDRP. In its SEC filings, Mylan repeatedly created the misimpression that the classification scheme for the purposes of the MDRP was highly complex, involved subjective judgments, and contained ambiguities. In fact, as Mylan admitted in other sections of its SEC filings, the classification scheme was simple and consisted of bright-line rules. Mylan created this misimpression because it knew, or recklessly disregarded, that its classification of the EpiPen was simply wrong.
- 11. Separately, Mylan also repeatedly misrepresented that there was no investigation into its classification of the EpiPen when in fact the Department of Justice launched just such an investigation in November 2014. Mylan is independently liable for these misrepresentations.
- 12. Second, Mylan also engaged in anticompetitive conduct during the Class Period in an attempt to prevent competition with the EpiPen. In 2013, Mylan's competitor, Sanofi-Aventis, introduced a product, the Auvi-Q, to compete with the EpiPen in the market for epinephrine autoinjectors. The Auvi-Q was a superior product to EpiPen in multiple ways; the product was designed to be flat and rectangular, so as to fit easily in purses and other places a smart-phone might fit, and the product included audible instructions that allowed users to

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operate the device in an emergency without having to focus on reading the directions. In response to this competitive threat, Mylan began to offer unprecedented rebates of 30% or more on the cost of the EpiPen to third-party payors, including commercial insurance companies and pharmaceutical benefit managers.

- 13. As a result of its anticompetitive conduct, Mylan successfully blocked Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine autoinjectors. In certain states where Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.
- 14. Mylan repeatedly failed to tell the whole truth about the ways in which it competed and about the reasons for its financial success, including in the market for epinephrine autoinjectors, by failing to disclose this anticompetitive conduct. While Mylan's conduct certainly violated U.S. antitrust laws, including Sherman Act Section 2, investors cared about this conduct in any event due to the significant liability to which it exposed Mylan.
- 15. Third, beginning in 2013 at the latest and continuing into the present, Mylan entered into anticompetitive agreements with its competitors in the generic drug market. In particular, Mylan agreed with its competitors to allocate the market for Doxy DR so that the drug companies, including Mylan, that manufactured Doxy DR would not compete against one another for major customers and so would not bring down the price of Doxy DR through competitive bids. Mylan also agreed with drug companies to fix the price of certain generic drugs, including albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, doxycycline monohydrate, glipizide-metformin and verapamil (the "Price-Fixed Drugs").
- 16. The evidence that Mylan engaged in this anticompetitive conduct is overwhelming. On December 14, 2016, the attorneys general of twenty states filed a joint

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complaint against Mylan that was the product of a years-long investigation.¹ In the complaint, the States detail the fruits of their investigation and tell the story, with great detail and relying on documentation, of how Mylan agreed to allocate the market for Doxy DR with its competitors. Mylan expressly agreed not to compete with other companies for the business of particular wholesalers of Doxy DR, and for years, Mylan acted in accordance with that agreement.

17. The evidence that Mylan colluded to fix the price of the Price-Fixed Drugs is likewise clear. The average prices of these drugs in the United States moved in near-perfect unison during the period of the conspiracy, and the prices of these drugs increased suddenly and simultaneously at each drug company at or near the start of that period. The price increases were exponential—the prices of multiple drugs, including for example clomipramine and propranolol increased suddenly by over 1000%. No other explanation for these sudden, synchronized price increases exists—there was no supply shortage or sudden increase in demand for these drugs during this period. Moreover, the market for generic drugs is highly susceptible to collusion for a number of reasons detailed below. For example, the markets for the Price-Fixed Drugs are dominated by only a few companies, and this market concentration makes collusion easy. The extreme price increases caused by this generic drug price-fixing cartel, in which Mylan is an active and important player, imposed, and continue to impose, a searingly unfair burden on nearly all residents of the United States, including children and the

¹ Counsel for Lead Plaintiffs contacted the Connecticut Attorney General's Office regarding the allegations set forth in their Complaint filed December 14, 2016, *see Connecticut v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056 (Dkt. No. 1) (D. Conn. Dec. 14, 2016) and the [Proposed] Consolidated Amended Complaint filed on October 31, 2017, *see Connecticut v. Aurobindo Pharma USA, Inc.*, No. 2:17-cv-03768 (Dkt. No. 3) (E.D. Pa. Oct. 31, 2017). A signatory of that Complaint at the Connecticut Attorney General's Office confirmed that the documents cited in the Complaint and the Consolidated Amended Complaint include those produced by Mylan, and that it has evidentiary support for its allegations against Mylan and Defendant Malik.

elderly, who, without exaggeration, rely on affordable generic drugs for their quality of life, and in some cases, their survival.

- 18. In this way, Mylan again misled investors about the competition it faced and about the validity of its sales figures. Mylan repeatedly stated to investors that the market for generic drugs was highly competitive. In fact, the market for at least some of the generic drugs Mylan sold was collusive, and lacked any real competition. Mylan's statements about the basis for its financial performance were also misleading because they failed to disclose that Mylan competed through anticompetitive means, and so failed to tell the whole truth about the bases for Mylan's financial success. Mylan's statements suggested that it did not compete through collusion with competitors on prices, when in fact it did, and while Mylan's collusion certainly violated U.S. antitrust laws, investors cared about such collusion in any event due to the significant liability to which it exposed Mylan.
- 19. When these frauds concealed by Mylan became known to the investing public, Mylan's stock dropped precipitously. In late August 2016, a news article detailed how Mylan had increased the price of the EpiPen over 500%, revealing the effects of Mylan's anticompetitive conduct and causing public outcry. U.S. Congresspersons then called on Congress and the FTC to investigate Mylan for anticompetitive conduct relating to the EpiPen. Upon this news and other related revelations, Mylan stock fell \$6.17, or 12.51% between August 19 and August 24, 2016. When the FTC announced on January 30, 2017 that it was investigating Mylan, Mylan's stock fell even further.
- 20. As more information about Mylan's frauds was revealed to the public, Mylan's stock price continued to fall. On September 2, 2016 *Inside Health Policy* published an article revealing that CMS had informed Mylan that the Company had incorrectly classified EpiPen as

a generic under the MDRP, and that Congress was asking CMS and Mylan for an explanation of the classification of the EpiPen as a generic drug. On October 5, 2016, Bloomberg published an article revealing CMS's response to the Congressional inquiry and its confirmation that Mylan had incorrectly classified the EpiPen for years. On this news, Mylan's share price fell \$1.95, or 4.65%, to close at \$39.97 on September 2, 2016, and fell \$1.19, or 3.13%, to close at \$36.84 on October 6, 2016.

- 21. On November 3, 2016, Bloomberg News reported that U.S. prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion. On December 14, 2016, Bloomberg reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, were "preparing to plead guilty to price-fixing charges," in a scheme that involved unnamed executives from Mylan. On January 10, 2017, The Philadelphia Inquirer published an article stating that Glazer and Malek had admitted to the charges of conspiring to manipulate prices of generic drugs. On this news, shares of Mylan fell \$2.53 or 6.9% on November 3, 2016, \$0.61 or 1.6% on December 14, 2016 and \$2.18 or 5.6% between January 10 and January 12, 2017.
- 22. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of 46 state attorneys general in which he announced that the group would be filing an amended complaint in their antitrust action against Mylan and attached the proposed amended complaint. The amended complaint contained extensive new allegations that Mylan participated in a wide-ranging price-fixing conspiracy, and for the first time named Rajiv Malik, Mylan's president and executive director, as an individual defendant for his direct

participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market and fix the price of generic drugs.

- 23. On this news, Mylan shares fell \$2.53, or 6.62%, to close at \$35.71 on October 31, 2017.
- 24. In total, upon the disclosures of Defendants' wrongful acts and omissions, the market value of Mylan has plummeted by more than \$5.5 billion. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Mylan's securities, Plaintiffs and other members of the Class suffered significant losses and damages.

II. JURISDICTION AND VENUE

- 25. The claims asserted herein arise under and pursuant to §§ 10(b), 14(e) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78n(e) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).
- 26. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.
- 27. Venue is proper in this Judicial District pursuant to § 27 of the Exchange Act and 28 U.S.C. §1391(b). Mylan N.V.'s stock trades on the NASDAQ-GS, located within this Judicial District.
- 28. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

- 29. Plaintiffs Menorah Mivtachim Insurance Ltd., Menorah Mivtachim Pensions and Gemel Ltd., Phoenix Insurance Company Ltd., Meitav DS Provident Funds and Pension Ltd., as set forth in the certifications attached as Exhibit B to the Declaration of Jeremy A. Lieberman (Dkt. 20), incorporated herein by reference, and Dan Kleinerman, as set forth in the certification attached as Exhibit B to the Declaration of Daniel S. Sommers (Dkt. 13), incorporated herein by reference, acquired Mylan securities on the NASDAQ at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures.
- 30. Defendant Mylan N.V. is incorporated in the Netherlands. Mylan N.V.'s principal executive offices are located at Building 4, Trident Place, Hertfordshire AL10 9UL, United Kingdom. Mylan, together with its subsidiaries, develops, licenses, manufactures, markets, and distributes generic, and specialty pharmaceuticals worldwide. The Company provides generic pharmaceutical products in tablet, capsule, injectable, transdermal patch, gel, cream, or ointment forms, as well as active pharmaceutical ingredients. Among other products, Mylan markets and sells the EpiPen, a branded device for injecting a measured dose of epinephrine by means of auto-injector technology to treat severe allergic reactions. Mylan Inc. is an indirect wholly owned subsidiary of Mylan N.V. Prior to February 27, 2015, Mylan Inc. preceded Mylan N.V. as the SEC registrant. In early 2015, Mylan Inc.'s business was reorganized under Mylan N.V. and led by the former officers and directors of Mylan Inc. On February 27, 2015, Mylan N.V. succeeded Mylan Inc. as the SEC registrant. Mylan N.V.'s common stock began trading on the Nasdaq Global Select Market ("NASDAQ-GS") on March 2, 2015 under the ticker symbol "MYL."
- 31. Defendant Mylan Inc. is incorporated in Pennsylvania. Mylan Inc.'s principal executive offices are located at 405 Lexington Avenue, Floor 52, New York, New York 10174.

- 32. Defendant Heather Bresch ("Bresch") has served as the Company's Chief Executive Officer ("CEO") since January 2012. From 2002 to 2005, Bresch served as Mylan's Director of Government Relations.
- 33. Defendant Robert J. Coury ("Coury") served as the Company's CEO from September 2002 to January 2012.
- 34. Defendant Paul B. Campbell ("Campbell") has served as the Company's Chief Accounting Officer since May 2015.
- 35. Defendant Rajiv Malik ("Malik") has served as the Company's President since January 01, 2012 and has served as an Executive Director since 2013.
- 36. Defendant Kenneth S. Parks ("Parks") has served as the Company's Chief Financial Officer ("CFO") since June 2016.
- 37. Defendant John D. Sheehan ("Sheehan") served as the Company's CFO from April 2010 to April 2016.
- 38. Defendants Bresch, Coury, Campbell, Malik, Parks and Sheehan are referred to collectively as the "Individual Defendants."

IV. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS OVERCHARGING MEDICAID FOR EPIPENS AND BY FAILING TO DISCLOSE THAT MYLAN WAS BEING INVESTIGATED FOR ITS EPIPEN CLASSIFICATION

A. The Importance of EpiPen to Mylan's Business

39. Ever since Mylan first acquired the EpiPen in 2007, the EpiPen has been enormously important to Mylan's business. As illustrated in the following table, during the Class Period, the EpiPen was responsible for between 28% and 95% of Mylan's operating profits—*i.e.*, profit earned from Mylan's normal, core business operations.

Operating Profit by Year (millions USD) ²							
	2012	2013	2014	2015	2016		
EpiPen	306	393	525	498	671		
Total Mylan	1,109	1,135	1,352	1,460	701		
% from EpiPen	27.59%	34.63%	38.83%	34.11%	95.64%		

- 40. The EpiPen's paramount importance to Mylan is also reflected in analyst reports covering the company, which, throughout the Class Period, devoted significant attention to the EpiPen and routinely tied Mylan's overall fortunes to the EpiPen.
- 41. For example, in a report dated August 24, 2016, RBC Capital Markets analyst Randall Stanicky noted that, "the importance of [EpiPen] to [Mylan's] P&L growth over the last several years has been well understood," and that "EPIPEN has been an important growth driver for MYL the last several years." JPMorgan analyst Chris Schott similarly noted in an October 4, 2016 report that "Epipen is Mylan's largest product at >\$1bn in sales." In fact, Morningstar's mere four-sentence profile of the company highlights the EpiPen by name, noting that after revenue from generics, "[r]emaining sales come from a handful of branded products, primarily the epinephrine injector EpiPen." The EpiPen is the only drug specifically mentioned by name. Indeed, in an October 18, 2016 report, Morningstar analyst Michael Zbinovec wrote that "Mylan's specialty drug franchise is essentially comprised entirely of EpiPen."

² EpiPen operating profits are taken from a September 2016 SEC filing made by Mylan specifically for the purpose of providing profitability information about the EpiPen, after Mylan gave testimony on that topic to Congress. That filing explained that "Mylan does not regularly provide profitability analyses for individual products and does not intend in the future to provide product level profitability [sic] analysis for EpiPen or to update this analysis." The figure for 2016 is an estimated figure. Total Mylan operating profits are taken from Mylan's Form 10-Ks, where they are reported as "Earnings from operations."

³ Randal Stanicky, Matthew Won & Ashley Ryu, *Our thoughts on negative EPIPEN pricing "headline": Direct read to MYL but also implications for TEVA and IPXL*, RBC Capital Markets (Aug. 24, 2016).

⁴ Chris Schott, Dana Flanders & Aditi Singhania, Mylan NV: Updating Estimates for Epipen; Remain Cautious In NT But Valuation Offers Compelling LT Entry Point, J.P.Morgan (Oct. 4, 2016).

⁵ Michael Waterhouse & Damien Conover, Mylan's EpiPen pricing blowback doesn't dramatically alter the company's significant challenges, Morningstar (Oct. 18, 2016); and Michael Zbinovec, Mylan is digesting Meda while facing EpiPen headline risk, Morningstar (Oct. 18, 2016).

- 42. EpiPen sales were also critically important to Mylan's quarterly earnings results and Mylan's ability to meet analyst expectations. For example, in a report dated February 11, 2016, BTIG analyst Timothy Chiang wrote that Mylan was "in need of EpiPen after weak Q4," to make up for a weaker than expected fourth quarter in 2015. ⁶ A few quarters later, when the Company beat expectations, analysts attributed the success to the EpiPen. For instance, in an August 9, 2016 report, Morgan Stanley analyst David Risinger noted that "Epipen drove EPS slightly above" expectations. ⁷ Similarly, in an August 10, 2016 report titled "Epipen takes the driver's seat," Barclays analyst Douglas D. Tsao concurred that "Epipen was clearly the big driver of 20 results." ⁸
- 43. EpiPen sales also drove analysts' ratings and evaluations of Mylan's financial prospects. Numerous analysts equated risks to the EpiPen business with risks to their evaluations of Mylan as a whole. For instance, JPMorgan analysts included "generic competition for Epipen" as one of three "[r]isks to the downside" for its overall rating of and price target for Mylan, in a March 1, 2016 report, an August 10, 2016 report, an October 4, 2016 report, and an October 10, 2016 report. Morgan Stanley analysts also repeatedly included "FDA approval of pharmacist-substitutable generic Epipen" as the first risk listed in a section titled "Risks to Achieving Price Target," including in a February 12, 2016 report and again in an

⁶ Timothy Chiang & Ben Shim, Mylan N.V.: In Need of Epipen After Weak Q4; Net Model w/ Meda Suggests Much Needed Accretion is Possible; Buy, BTIG (Feb. 11, 2016).

⁷ David Risinger, et al., *Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

⁸ Douglas D. Tsao & Morgan Williams, Mylan Inc.: Epipen takes the driver's seat, Barclays (Aug. 10, 2016).

⁹ Chris Schott, et al., MYL/TEVA: Positive Epipen News Supports EPS Upside for MYL, J.P.Morgan (March 1, 2016); Chris Schott, et al., Mylan NV: Solid Qtr Lead by Epipen; Long-Term Growth Trajectory Remains Intact, J.P.Morgan (Aug. 10, 2016); Chris Schott, et al., Mylan NV: Updating Estimates for Epipen; Remain Cautious in NT But Variation Offers Compelling LT Entry Point, J.P.Morgan (Oct. 4, 2016); and Chris Schott, et al., Mylan NV: Epipen Rebate Settlement and Updated Guidance A Positive, J.P.Morgan (Oct. 10, 2016).

August 9, 2016 report.¹⁰ BTIG analysts similarly stated that the one of the three "key risks" to its evaluation of Mylan were "Epipen revenues not meeting estimates," in a January 21, 2016 report and again in an August 29, 2016 report.¹¹

- 44. During the Class Period, Mylan's sales of EpiPen through Medicaid accounted for a very significant amount of Mylan's total sales of the EpiPen. In an October 10, 2016 report, UBS analyst Marc Goodman estimated that "Medicaid spending on EpiPen is ~35% of [Mylan's total] 2015 [EpiPen] sales." ¹²
- 45. As Mylan's sales of EpiPen constituted a massive part of Mylan's business, and as sales of EpiPen through Medicaid accounted for a very significant part of Mylan's EpiPen sales, Mylan's classification of the EpiPen for the purposes of the Medicaid Drug Rebate Program was highly consequential to the Company.

B. Legal Classification of Drugs for the Purposes of the Medicaid Drug Rebate Program

- 46. Medicaid is a U.S. government insurance program for persons whose income and resources are insufficient to pay for health care. Jointly funded by the state and federal governments, Medicaid is the largest source of funding for medical and health-related services for Americans with low income.
- 47. The Medicaid Drug Rebate Program ("MDRP"), which was created as part of the Omnibus Budget Reconciliation Act of 1990 (the "1990 Act"), requires a drug manufacturer to

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¹⁰ David Risinger, et al., Mylan: Epipen 4Q sales hurt by inventory workdown, not price adjustments as we hypothesized, Morgan Stanley (Feb. 12, 2016); and David Risinger, et al., Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings, Morgan Stanley (Aug. 9, 2016).

¹¹ Timothy Chiang & Ben Shim, *Mylan N.V.: Upping Estimates to Reflect Higher Epipen Sales; Buy*, BTIG (Jan. 21, 2016); and Timothy Chiang, *Mylan N.V.: MYL to Launch Authorized Generic Version of Epipen*, BTIG (Aug. 29, 2016).

¹² Marc Goodman, *Mylan Inc.: We're Still Constructive on MYL*, UBS (Oct. 10, 2016). This estimate relied on the October 5, 2016 letter to Senator Ron Wyden from CMS Acting Administrator Andrew M. Slavitt, which reported that total Medicaid spending on EpiPen from 2011 to 2015 was \$960 million, with \$253 million spent in 2014 and \$365 million in 2015.

enter into, and have in effect, a rebate agreement with the Centers for Medicare & Medicaid Services ("CMS") in order to receive state Medicaid coverage of the manufacturer's drugs. The rebate agreement imposes reporting and rebating requirements on the drug manufacturers. Manufacturers are required to identify all their covered outpatient drugs to CMS and provide CMS pricing data on those drugs. Manufacturers are then responsible for paying a rebate for their covered drugs that have been purchased and dispensed under state Medicaid plans. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program.

- 48. The purpose of the MDRP is to ensure that pharmaceutical companies grant appropriate bulk-discounts to government purchases of prescription drugs that are commensurate with the massive volume of these purchases. CMS, which is part of the Department of Health and Human Services (HHS), administers Medicaid in partnership with state governments.
- 49. However, in creating the MDRP, lawmakers recognized that generic drugs, which generally face significant competition from competitors, are less "overpriced" than brand drugs, which are usually patented and unique. Whereas competition usually will bring down the prices of generic drugs to close to the cost to the manufacturers of producing those drugs, market forces will not similarly bring down the price of brand drugs, which are patented or otherwise face no direct competition. Accordingly, lawmakers required drug manufacturers that participate in MDRP to provide a greater rebate for patented drugs and drugs that otherwise face no competition than for generic drugs, which the government already buys at close-to-cost prices.

50. Drug manufacturers are responsible for correctly classifying their drugs and paying the correct rebate amounts for their drugs under the MDRP. This classification is not complicated. From the very beginning of the MDRP in 1990 to the present, the enabling statute and regulations governing the MDRP have only ever allowed three possible classifications for a drug like the EpiPen for the purposes of the MDRP: (1) a single source drug ("S" drug); (2) an innovator multiple source drug ("I" drug); and (3) a noninnovator multiple source drug ("N" drug).¹³ The rule for classifying drugs under the 1990 Act, which has not changed since its enactment, is simple and unambiguous: drugs that are approved under an original new drug application ("NDA") must be classified as either "S" or "I" drugs, while drugs that are not approved under an original new drug application (such as those approved under an abbreviated new drug application) must be classified as "N" drugs." An NDA is the application drug manufacturers use to obtain approval to market a new drug, which is generally subject to a patent, whereas an ANDA is the application generic drug manufacturers use to seek approval to market a generic version of a drug already introduced to the market after gaining approval under an original new drug application. Therefore, under the 1990 Act, all drugs that are approved under NDAs (which are generally patented brand drugs) must be classified as S or I drugs, whereas all drugs that are approved under ANDAs (which are generic drugs) are classified as N drugs. No exceptions to this rule are present in the language or intent of the 1990 Act.

¹³ 42 U.S.C. § 1396r–8(k)(7).

¹⁴ In the language of the statute, a single source drug or S drug is "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration" 42 U.S.C. § 1396r–8 (k)(7). An innovator multiple source drug or I drug is "a multiple source drug [*i.e.*, a drug that has at least one other "therapeutically equivalent" drug] that was originally marketed under an original new drug application approved by the Food and Drug Administration. *Id.* A noninnovator multiple source drug or N drug is "a multiple source drug that is not an innovator multiple source drug [*i.e.*, is not a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration]." *Id.*

- 51. As for classifying drugs approved under NDAs as either S or I drugs, a drug approved under an NDA must be classified as an I drug if the FDA has determined that the drug has at least one other "therapeutic equivalent," *i.e.*, another drug available in the United States that offers the same therapeutic benefits as the drug being classified. However, this distinction is insignificant for the purposes of the determining the rebate amount owed under the MDRP—all S or I drugs are subject to the same higher rebate calculations than that to which N drugs are subject.
- drug was approved for marketing under an NDA in order to classify that drug correctly for the purposes of rebates under the MDRP, a second unambiguous, bright line rule in the statutory language also makes classification simple: *in no event* can a drug that does not face competition from any therapeutically equivalent drug be classified as a generic or N drug; that is, if a drug is the only drug on the market that, according to the FDA, offers the same therapeutic benefits that it does, that drug cannot be a generic or N drug. Under 42 CFR 447.509, as relevant for the purposes of this complaint, for a drug to be classified as an N drug there must be "at least one other drug product which [...] [i]s rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations')." That is, under the 1990 Act, a drug has a therapeutic equivalent if such an equivalent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." The Orange Book is not hard to find—it has been available in the FDA's public reading room

since 1990, and has been available on the FDA's website, in searchable form, since at least 2007.¹⁵

- 53. On October 1, 2007, the first regulations promulgated pursuant to the 1990 Act, 42 CFR 447.500 et seq., became effective (the "2007 Regulations"). These regulations largely adopted the statutory definitions of S, I and N drugs, and for the purposes of this complaint, made only one small change to the classification scheme detailed in the 1990 Act: S or I drugs include, in addition to all drugs approved under an NDA, drugs "approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA)." These applications are used only for certain medical products, such as vaccines, antibiotics, certain antibodies, blood and blood by-products, tissue and cellular products; these applications are not used for drugs for the treatment of anaphylaxis. Accordingly, under the 2007 Regulations, the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remained unchanged; the 2007 Regulations simply expanded the bright line rule by making clear that in addition to all drugs approved under NDAs, all drugs approved under BLAs, PLAs, ELAs and ADA must also be classified as S or I drugs.
- 54. On at least two occasions since 2007, CMS has issued guidance regarding the proper classification of drugs under the MDRP. Given that the classification of drugs for the MDRP is extremely straightforward, in both instances, CMS's guidance constituted exactly one

¹⁵ The current version of the Orange Book may be found at http://www.fda.gov/cder/orange/default.htm.

¹⁶ 42 CFR § 447.502 (2007)

paragraph. On January 5, 2010, CMS informed drug companies in Manufacturer Release No. 80.¹⁷

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).

55. On September 12, 2014, CMS repeated the same guidance quoted above in Manufacturer Release No. 91:

In general, covered outpatient drugs that are approved under a new drug application (NDA) should be reported to CMS as either "S" or "I" drugs, while drugs approved under an abbreviated new drug application (ANDA) should be reported to CMS as "N" drugs.¹⁸

- 56. The "in general" language in the above-quoted paragraphs is superfluous. No exception to the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP exists in the statutory language of the 1990 Act or in the 2007 Regulations.¹⁹
- 57. In February 2016, CMS published a Final Rule modifying slightly the definitions of S, I and N drugs found in the 2007 Regulations (the "Final Rule").²⁰ The Final Rule became effective April 1, 2016 (the "2016 Regulations").²¹ Under the 2016 Regulations, the basic bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remains unchanged, but the 2016 Regulations introduced a bright line

¹⁷ Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 80* (Jan. 5, 2010), at 3.

¹⁸ Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91* (Sept. 12, 2014), at 3.

¹⁹ Moreover, industry practice and the practice of CMS is to classify a drug delivery product filed under a new drug application as an S or I drug, even if any patents covering the substance delivered by the product have expired.

²⁰ Final Rule, 81 Fed. Reg. 5170 (Feb. 1, 2016).

²¹ 42 CFR § 447.509 (2016).

exception to the rule: an NDA need not be classified as an S or I drug if and only if, following the effective date of the 2016 Regulations (April 1, 2016), a drug marketer requests that CMS treat a drug approved under an NDA as if it were approved under an ANDA for the purposes of the MDRP, and CMS then expressly determines that a "narrow exception" applies to that drug and grants the drug manufacturer leave to classify the drug as an N drug.²² Notably, certain classes of drugs are categorically excluded from this "narrow exception." In guidance published alongside the Final Rule, CMS stated, "the narrow exception will not be considered applicable to drugs . . . that received patent protection or statutory exclusivity."²³

- 58. In summary, from the beginning of the MDRP in 1990 until April 1, 2016, applicable law and regulations required all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP. After April 1, 2016, applicable regulations require all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP, unless CMS finds after April 1, 2016 that a narrow exception applies, and a narrow exception will never apply to drugs that have received patent protection. Moreover, at no point have applicable laws or regulations permitted a drug that does not face competition from any therapeutically equivalent drug to be classified as a generic or N drug.
- 59. The difference in rebate amounts owed for generic and non-generic drugs is significant. In general, under current regulations, drug manufacturers must pay CMS a rebate of 23.1% of the average manufacturer price of patented drug classified as an S or I drug, yet the manufacturer need pay a rebate of only 13% of the average manufacturer price of a generic or N

²² In the language of the 2016 Regulations, in the definitions of S and I drugs, "an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies."

²³ 81 Fed. Reg. 5170, 5191 (Feb. 1, 2016). As explained *infra*, this "narrow exception" cannot apply to Mylan's classifications during the Class Period because: (1) a request for the exception could only be made after the effective date of the 2016 Regulations; (2) to date Mylan has not requested that this "narrow exception" apply to the EpiPen; and (3) in any event, the exception cannot apply to the EpiPen because the EpiPen has "received patent protection."

drug.²⁴ A drug manufacturer reaps a substantial financial benefit if it classifies a drug as a generic or N drug for the purposes of the MDRP. Indeed, as explained below, Mylan was able to overcharge Medicaid by over \$700 million as a result of its misclassification of the EpiPen as a generic drug.

C. History of Classifications of EpiPen for the Purposes of the Medicaid Drug Rebate Program

- 60. The emergency drug autoinjector pen was first invented in the mid-1970s at Survival Technology in Bethesda, Maryland by Sheldon Kaplan. Initially, his device was called the ComboPen, and was purchased by the military for soldiers to use to autoinject nerve agent antidote in the event of chemical warfare. Kaplan and others eventually recognized that the same autoinjection technology, covered by U.S. Patent No. 4031893, among others, could be used to deliver epinephrine to treat anaphylaxis, and developed the EpiPen for that purpose. In the late 1980s, Survival Technology submitted the EpiPen to the FDA for approval under an NDA, and on December 22, 1987, the FDA approved the NDA, Number 019430, and permitted the EpiPen to be marketed in the United States.
- 61. When the EpiPen first was reported to CMS for the purposes of the MDRP, the EpiPen was classified accurately as a non-generic S drug.²⁵ As explained above, under the 1990 Act, all drugs that are approved under NDAs must be classified as S or I drugs. The EpiPen was approved under an NDA, so Survival Technology had to classify it as an S or I drug. Survival Technology accurately classified the drug as an S drug because the drug had no FDA-approved therapeutic equivalents (nor has it ever had any therapeutic equivalents).

²⁴ 42 CFR § 447.509 (2016).

²⁵ Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator (Oct. 5, 2016) at 2.

62. In 1996, Survival Technology merged with Brunswick Biomedical to form Meridian Medical Technologies Inc. ("Meridian"), and in 1997, Dey Inc. ("Dey"), a subsidiary of Merck KGaA ("Merck"), acquired the exclusive right to market and distribute the EpiPen from Meridian.²⁶

D. Mylan Knowingly or Recklessly Misclassified the EpiPen for the Purposes of the MDRP Ever Since It Began Selling the EpiPen to Medicaid.

- On October 2, 2007, Mylan acquired exclusive rights to market the EpiPen from Dey and Dey's parent company Merck, as part of its acquisition of Merck's generics business. Meridian retained ownership of the patents relating to the EpiPen. Mylan continued Dey's sales of EpiPen to Medicaid. From October 2, 2007 to the present, the responsibility of correctly classifying the EpiPen for the purposes of the MDRP shifted to Mylan.
- 64. As the following facts make clear, from 2007 to the present, Mylan knowingly or recklessly misclassified the EpiPen as a generic N drug for the purposes of the MDRP.

1. Proper Classification of the EpiPen As a Brand Drug Is Straightforward Under Applicable Laws and Regulations

- 65. While Mylan is a massive multinational corporation valued at billions of dollars, and had an army of sophisticated lawyers available to provide advice in 2007 and thereafter on the proper classification of the EpiPen, the proper classification of the EpiPen required no sophisticated legal expertise at all.
- 66. Mylan's classification of the EpiPen as a generic N drug for the purposes of the MDRP was manifestly contrary to the 1990 Act and to the 2007 Regulations, both of which clearly required that all drugs that are approved under NDAs must be classified as S or I drugs.

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²⁶ Meridian was acquired in January 2003 by King Pharmaceuticals, which was then acquired by Pfizer, Inc. ("Pfizer") in 2010; accordingly, Meridian is now a subsidiary of Pfizer. Pfizer, through Meridian, currently owns the non-expired patents on the EpiPen and currently manufactures the EpiPen for Mylan, while Mylan has exclusive rights to sell and market the EpiPen.

The question whether a drug was approved under an NDA is not a puzzle—if Mylan somehow did not gather from Dey the application type under which the EpiPen was approved, Mylan easily could have looked up the application type through the FDA, including through a simple online search.²⁷ As the EpiPen was approved under an NDA, the 1990 Act and the 2007 Regulations required Mylan to classify the EpiPen as an S or I drug.

67. While there was no ambiguity in this classification requirement, the 1990 Act and the 2007 Regulations also make clear that in no event may a drug that has no FDA-approved therapeutic equivalent be classified as an N drug. Again, whether a drug has an FDA-approved therapeutic equivalent is not a puzzle—under the 1990 Act as drug has a therapeutic equivalent if such an equivalent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." The text of the 2007 Regulations themselves included a government website address drug manufacturers could visit to determine whether a drug had a therapeutic equivalent:

For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at http://www.fda.gov/cder/orange/default.htm or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857;

68. The EpiPen has never had an FDA-approved therapeutic equivalent. In fact, in recent years Mylan filed a citizen's petition with the FDA in which it argued that the epinephrine autoinjector from a competitor, Teva Pharmaceutical Industries Ltd. ("Teva"), was not therapeutically equivalent to the EpiPen. Mylan argued that Teva's autoinjector lacked certain patented features of the EpiPen and required the user to remove two caps in order to use

²⁷ The application type is appears at U.S. Food and Drug Administration, Drugs@FDA: FDA Approved Drug Products, *available at* http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430 (last visited March 20, 2017).

the device correctly, whereas the EpiPen required the user to remove only one cap before use. Mylan submitted data from studies that, according to Mylan, indicated that users accustomed to use of the EpiPen would not reliably use Teva's autoinjector correctly in an emergency due to these differences and others in the designs of the injectors. Mylan expressly argued that a difference in the design of an injector can create a therapeutic advantage for one product over another, even if the two products are both injectors of the same drug. The FDA ultimately determined that Teva's epinephrine autoinjector was not therapeutically equivalent to the EpiPen.

- 69. As the EpiPen has never had an FDA-approved therapeutic equivalent, the EpiPen cannot be classified as a generic N drug under the 1990 Act and the 2007 Regulations. For this additional reason, Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations.
 - 2. Mylan and the Individual Defendants Repeatedly Affirmed in SEC Filings the Simple Rule that Drugs Approved Under an NDA Are Brand Drugs for the Purposes of the MDRP
- 70. Mylan and the Individual Defendants knew or recklessly disregarded that Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations. In Mylan's 10-K filings throughout the Class Period, Mylan admitted that:

The required rebate [under the MDRP] is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs required manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

In these SEC filings, Mylan, and the Individual Defendants who signed them, made clear that they understood the MDRP to require drug companies to rebate products based entirely on whether those products were marketed under NDAs or under ANDAs. As the EpiPen was marketed under an NDA, Mylan's own SEC disclosures imply that Mylan was required to give Medicaid the greater rebate applicable to brand drugs (of approximately 23% of the average manufacturer's price) for the EpiPen.

3. CMS Expressly Informed Mylan Prior to the Start of the Class Period That Mylan's Classification of the EpiPen Was Incorrect

71. CMS expressly told Mylan that its classification of the EpiPen as a generic N drug was incorrect. On March 12, 2009, following the release of a report prepared by the HHS Inspector General ("HHS IG") titled "Accuracy of Drug Categorizations for Medicaid Rebates," CMS staff requested the HHS IG to provide it with a list of the eight drugs the HHS IG had determined to be incorrectly classified for the purposes of the MDRP in the course of its preparing the report. In response to this request, on March 16, 2009 the HHS IG provided CMS with the list of misclassified drugs, and that list included the EpiPen. Subsequently, CMS notified Mylan about the misclassification. As CMS Acting Administrator Andrew M. Slavitt stated in a letter to Senator Ron Wyden, "The Center for Medicaid and CHIP Services in CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that [the EpiPen] is incorrectly classified."²⁸ As CMS itself was expressly informed by the HHS IG on March 16, 2009 that the EpiPen was misclassified for the purposes of the MDRP, on information and belief, CMS was not derelict in performing its duties and told Mylan that the EpiPen was misclassified for the purposes of the MDRP shortly after having that misclassification highlighted to it by the HHS IG, and well before the start of the Class Period.

²⁸ Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator (Oct. 5, 2016) at 2.

- 4. Since 2004, Four New Patents Covering the EpiPen Have Been Granted, and Mylan Has Vigorously Participated in the Enforcement of Those Patents
- 72. Events in the years following Mylan's initial classification of the EpiPen as an N drug further demonstrate that its misclassification was knowing or, at a minimum, extremely reckless. Since 2004, Meridian Medical Technologies, Inc. ("Meridian") has received four additional patents for features that were subsequently integrated into the EpiPen: U.S. Patent Numbers 7,449,012, 7,794,432, 8,048,035, and 8,870,827 (the "EpiPen Patents"). These four patents have a priority date (*i.e.*, the date used to establish the novelty and/or obviousness of a particular invention relative to prior art) of August 6, 2004, and all will expire in 2025. These patents substantially altered the product Mylan acquired from Dey. As Mylan spokeswoman Lauren Kashtan has stated, "As anyone who has used the product knows, the epinephrine auto-injector we have in the market today is substantially different than the one we acquired." 29
- 73. The issuance of the EpiPen Patents, and Mylan's designation of these patents as covering the EpiPen, further show that Mylan was acting disingenuously in classifying the EpiPen in effect as a generic rather than as a brand drug for the purposes of the MDRP. Mylan's disingenuousness is underscored by the fact that Mylan vigorously and repeatedly sought to enforce these patents by participating in multiple lawsuits challenging potential generic competitors to EpiPen.
- 74. In 2009, Meridian and Mylan filed a patent lawsuit ("2009 Lawsuit") against Teva, which was preparing to introduce an epinephrine auto-injector that would compete with EpiPen. The 2009 Lawsuit accused Teva of seeking to "manufacture and sell a generic version of . . . [the] highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent Nos.

²⁹ Intelligent Investments, *Mylan:* \$5 Billion Potential Liability from EpiPen Underpayment of CMS Rebates, Seeking Alpha, at 6 (Feb. 6, 2017) (quoting statement made to NBC News).

7,449,012 B2 (the "'012 patent") and 7,794,432 B2 (the "'432 patent"), which expire on September 11, 2025.

- 75. The 2009 Lawsuit noted that Meridian was "the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3mg/0.3 mL and 0.15 mg/0.3 mL ('EpiPen® Autoinjector')." It also noted that Meridian had "submitted information concerning the '012 patent and '432 patent for listing in the FDA's [Orange Book] on July 17, 2009 and September 15, 2010, respectively." The 2009 Lawsuit further claimed that Teva's application to the FDA for its classification of its proposed product "constitute[d] an act of infringement" of the EpiPen Patents at issue.
- 76. A similar lawsuit was filed in 2010 against Sandoz, Inc. ("Sandoz") ("2010 Lawsuit"). The 2010 Lawsuit challenged the proposed "manufacture and s[ale] [of] a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector," and asserted the same patents as the 2009 Lawsuit. Like the 2009 Lawsuit, the 2010 Lawsuit asserted that Sandoz's application to the FDA for its proposed product "constitute[d] an act of infringement" of the EpiPen Patents at issue.
- 77. In 2011, yet again, Mylan, in concert with Meridian, asserted the EpiPen Patents, this time in a lawsuit ("2011 Lawsuit") against Intelliject, Inc. ("Intelliject"). Like Teva and Sandoz before it, Intelliject sought to introduce a competitor to EpiPen. Like the 2009 and 2010 Lawsuits, Mylan, in concert with Meridian and King, asserted the EpiPen patents to prevent Intelliject from proceeding in marketing its product, and argued that Intelliject's application to the FDA "constitute[d] an act of infringement" of the EpiPen Patents at issue.

5. In 2014, the DOJ Issued a Subpoena to Mylan Regarding Mylan's Misclassification of the EpiPen

78. In November 2014, Mylan received a subpoena from the DOJ as part of the DOJ's investigation into "whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs." Accordingly, by November 2014 at the very latest, the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan's classification of the EpiPen for the purposes of the MDRP was potentially incorrect.

6. Mylan Marketed the EpiPen as a Brand Name Drug

- 79. Mylan's classification of the EpiPen as a generic drug is also in obvious tension with Mylan's treatment of the EpiPen as a brand drug for all purposes other than the classification of this drug under the MDRP. After acquiring the right to the EpiPen, Mylan embarked on a years-long marketing campaign with the express purpose of promoting the EpiPen as an irreplaceable, unequalled, life-saving brand-name drug. That campaign has resulted in the EpiPen brand being compared to "Kleenex" amongst doctors, according to a 2015 Bloomberg article. Indeed, in August 2015, Bresch touted "the brand equity with EpiPen" as a reason not to worry about the prospect of impending generics.
- 80. Further, Mylan tacitly acknowledged that one of the reasons for the EpiPen's skyrocketing prices is that the EpiPen is a brand-name drug, and not a generic drug. Specifically, in December 2016, in the wake of controversy over EpiPen's rising prices, Mylan introduced an "authorized generic" to the EpiPen priced at \$300, less than half the EpiPen's list price. Such a measure would not have been needed were the EpiPen truly a generic drug, as

³⁰ Mylan N. V., Quarterly Report (Form 10-Q) at 56-57, (Nov. 9, 2016).

Mylan claimed it to be in classifying the EpiPen as a generic N drug for the purposes of the MDRP.

81. Mylan wanted to have it both ways—it wanted to be able to charge the high prices commensurate with brand-name drugs, while reimbursing the government as little as possible under a classification intended to account for the lower profit margins associated with generic drugs. For years, Mylan succeeded in doing so.

E. Mylan Knowingly or Recklessly Misled Investors Concerning its Misclassification of the EpiPen

Throughout the Class Period, Mylan misled investors about its misclassification 82. of the EpiPen. In its annual and quarterly filing with the SEC, Mylan repeatedly and intentionally and/or recklessly led investors to believe that the classification of its drugs for the purposes of the MDRP was "complex and often involve[d] subjective decisions," and was subject to "risk of errors and differing interpretations." Moreover, Mylan repeatedly stated that there could be "ambiguity with regard to how to properly calculate . . . payments to Medicaid." These statements failed to disclose the true situation Mylan faced with respect to its classification of the EpiPen, namely that Mylan's classification of the EpiPen was blatantly incorrect under applicable law and regulations. The classification of the EpiPen was not complex and did not involve subjective decisions—as explained above, the classification was simple and straightforward and turned simply on whether the drug at issue had been approved under an NDA (a yes or no matter that can be determined by looking on a government website), and whether the drug had therapeutic equivalents (also a yes or no matter that can be determined by looking on a government website). And the classification was not subject to a "risk of error"—that risk of error had materialized, as Defendants knew or were reckless in not knowing that the EpiPen was incorrectly classified. Likewise, the classification was not subject to

"differing interpretations"—looking on the FDA website to check whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise.

83. These and Defendants' numerous other misleading statements regarding its misclassification of the EpiPen are detailed in Part VII infra.

F. Mylan Knowingly Misled the Public by Implying Mylan Was Not Being Investigated for Its EpiPen Classification When in Fact It Was

- 84. Separately and independently, Mylan misled investors regarding whether a government authority had taken a position contrary to positions Mylan had taken regarding its classification of the EpiPen, and whether Mylan was being investigated for its EpiPen classification.
- 85. Throughout the Class Period in its quarterly and annual filings, Mylan stated that "should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken " These statements were misleading from the start of the Class Period because, as explained above, prior to the Class Period CMS had informed Mylan that its classification of the EpiPen was incorrect. Accordingly, there was not merely a possibility that a government agency might take a position contrary to Mylan's regarding its classification of the EpiPen—rather, a government agency had already taken a contrary position on that subject and had conveyed its contrary position to Mylan.
- 86. Moreover, on and after November 2014, Mylan's statements that a government agency "may take a position contrary to a position we have taken" became doubly misleading because as of that date, the DOJ already had commenced an investigation relating to Mylan's misclassification of the EpiPen. That is, by November 2014, the DOJ had indicated to Mylan

that it had taken a position contrary to Mylan's with respect to Mylan's classification of the EpiPen, namely, that there was a substantial likelihood that Mylan had misclassified the EpiPen.

- 87. Mylan also misled investors concerning whether it was being investigated for its EpiPen classification. From the beginning of the Class Period, and in particular from November 2014 until November 2016, Mylan stated in its annual and quarterly SEC filings that "[a]ny failure to comply with [its payment obligations related to Mylan's participation in Medicaid] could subject us to investigation" In stating that Mylan was subject to a risk of investigation for a failure to comply with its Medicaid payment obligations, including a failure to comply with its obligation to classify the EpiPen correctly for the purposes of the MDRP, without also disclosing that that risk already had materialized when the DOJ commenced an investigation into Mylan's classification of the EpiPen, Mylan misled investors to believe that no such investigation was underway when in fact it was.
- 88. These and Mylan's numerous other misleading statements regarding whether a governmental authority had taken a position contrary to its own regarding its classification of the EpiPen and regarding the existence of an investigation into Mylan's classification are detailed in Part VII infra.

G. Mylan's Misclassification of the EpiPen and the Significance of the Misclassification Were Revealed Starting in September 2016

89. Starting in September 2016, the truth about Mylan's misclassification of the EpiPen for the purposes of the MDRP, and the significance of that misclassification for Mylan's finances, was revealed to the market over a series of months. Some of these revelations are as follows.

1. A Bipartisan Group of U.S. Senators Requested that the DOJ Investigate Mylan's Classification of the EpiPen

90. In a September 2016 letter, Senators Richard Blumenthal (D-Conn), Senator Chuck Grassley (R-Iowa) and Senator Amy Klobuchar (D-Minn), called on Attorney General Loretta Lynch to investigate Mylan's classification of the EpiPen for the purposes of the MDRP. The letter noted that the EpiPen had not faced any FDA-approved competitors and that Mylan actively had prevented other drug marketers from introducing competing products; the letter concluded that the EpiPen was an "innovator drug" subject to the higher rebate under the MDRP. The letter stated that the facts "suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes."

2. Mylan Agreed To Pay a \$465 Million Settlement with the DOJ over Its Misclassification of EpiPen

- 91. On October 7, 2016, Mylan announced in a press release that it had agreed to the terms of a \$465 million settlement with the DOJ and other government agencies "that w[ould] resolve questions that ha[d] been raised about the classification of . . . EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program." The press release explained that "the question in the underlying matter was whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs." The press release further stated that the settlement terms would resolve claims over "whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula."
- 92. According to numerous press reports, the settlement terms also required Mylan to pay a higher rebate rate for EpiPen to Medicaid starting on April 1, 2017.

- 93. Following Mylan's press release, numerous members of Congress criticized the purported DOJ settlement with Mylan for being excessively lenient. For example, on October 21, 2016, Senator Elizabeth Warren called the announced settlement "shamefully weak" and "shockingly soft." According to Senator Warren, the announced settlement size was too small, and may have "rewarded" Mylan by allowing it to keep an additional \$65 million that it had made by "defrauding Medicare and Medicaid." Senator Warren determined that Mylan has underpaid at least \$530 in Medicaid rebates, and financial analysts have determined that Mylan's underpayments were even greater. Senator Richard Blumenthal of Connecticut similarly called on the Justice Department to reject the announced settlement.
- 94. On August 17, 2017, Mylan finalized an agreement with the DOJ to pay \$465 million to settle the government's claims that Mylan misclassified the EpiPen to overcharge Medicaid by up to \$1.27 billion. Mylan announced this agreement in a press release issued the same day.
- 95. In the press release, Mylan effectively admitted that the EpiPen was misclassified by agreeing to reclassify the EpiPen as a brand-name "innovator" drug. The press release stated, "Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017."

3. The SEC Opened an Investigation into Mylan Regarding Its Classification of the EpiPen in October 2016

96. The same day Mylan announced its purported settlement with the DOJ, October 7, 2016, Mylan received "a document request from the Division of Enforcement at the SEC

³¹ According to Evercore ISI senior analyst Umer Raffat, Mylan may have shortchanged Medicaid \$707 million over the past five years.

seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints."

97. Mylan did not disclose this SEC document request until a month later, in its Form 10-Q filed with the SEC on November 9, 2016.

V. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN ANTICOMPETITIVE CONDUCT TO ALLOW IT TO INFLATE THE PRICE OF THE EPIPEN

- 98. Beyond Mylan's overcharging Medicaid for over a decade for its purchases of the EpiPen, Mylan engaged in anticompetitive conduct during the Class Period in an attempt to hinder competition against the EpiPen. Among other conduct, Mylan offered unusually large rebates (30% and higher) to third-party payors in the medical insurance market and expressly conditioned those rebates on the payors' dealing exclusively with Mylan.
- 99. Mylan misled investors by failing to disclose this anticompetitive conduct and the risk this conduct created that Mylan ultimately would be investigated for such conduct. When this conduct was revealed and when the risk of scrutiny of the Company's practices materialized, Mylan's stock dropped precipitously, injuring Plaintiffs and the Class.

A. The Market for Epinephrine Autoinjectors

- 100. Mylan has monopoly power in the market for epinephrine autoinjectors. Since Mylan acquired EpiPen, the product has accounted for more than 90% of the U.S. market for these devices. Mylan's monopoly power allows it to raise prices without losing sales. As noted above, Mylan has increased the price for EpiPen more than 500% since it acquired the rights to the device.
- 101. The overwhelming majority of patients in the U.S. who purchase epinephrine autoinjectors do so using their insurance coverage for prescription drugs. Accordingly, from 2013 to 2015, commercial insurance companies and pharmaceutical benefit managers (who

manage the pharmacy benefits of group health plan sponsors) (together "commercial third-party payors" or "third-party payors") accounted for 71% of the market for epinephrine autoinjectors in the U.S. State-based Medicaid plans accounted for an additional 16% of the market.

102. Given the dominance of commercial third-party payors in the market for epinephrine autoinjectors, a drug company seeking to enter this market must have its drug included on the lists of drugs maintained by commercial insurance companies and pharmaceutical benefit managers for which patients will be reimbursed (their "formularies"). These formularies are usually tiered, such that drugs are placed on different levels according to the amount of co-payment patients are required to pay. As consumers prefer to pay as little as possible out of pocket for their medications, consumers are incentivized to select drugs on tiers with lower co-pays. If a drug is wholly excluded from a third-party payor's formulary, the drug is not covered and is often too expensive for patients subject to that formulary to purchase without coverage. Prior to 2013, third party payors covered all available epinephrine autoinjectors (albeit at different tiers), but never excluded particular epinephrine autoinjectors from coverage entirely.

B. Mylan Excluded Sanofi from the Market for Epinephrine Autoinjectors by Offering Anticompetitive Rebates to Third-Party Payors Conditioned on Excluding Sanofi's Auvi-Q

103. In January 2013, the drug company Sanofi-Aventis U.S. LLC ("Sanofi") introduced an epinephrine autoinjector, the Auvi-Q, to compete with the EpiPen. Sanofi sold the Auvi-Q for roughly the same price as that of the EpiPen. The Auvi-Q was a superior autoinjector to the EpiPen in several ways. The device was smaller than the EpiPen and was easier to carry in pockets or bags because its design was flatter than that of the EpiPen. The Auvi-Q was also easier to operate than EpiPen—the device issued audible voice instructions to permit first-time users or users panicking from an anaphylactic emergency to operate the device

correctly without having to read instructions. The market welcomed this innovative device, and Auvi-Q sold successfully in the first few months following its release.

104. Mylan responded to this new competitive threat by excluding the Auvi-Q from the market. Shortly following the release of the Auvi-Q, Mylan began offering massive rebates to third-party payors on the express condition that the third-party payors not include the Auvi-Q in their formularies among the epinephrine autoinjectors for which those payors would provide reimbursement. Mylan specifically targeted Auvi-Q by requiring third-party payors to exclude Auvi-Q, while allowing certain other epinephrine autoinjectors (deemed not to be a threat to EpiPen) to remain on some third-party payors' formularies. These rebates amounted to 30% or more of the price that Mylan otherwise would have offered. Mylan did not typically offer rebates for EpiPen, and when it did so, those rebates were generally low, usually below 10%. Mylan had no legitimate business reason to offer these unprecedented, deep rebates conditioned expressly on excluding the Auvi-Q from the market; they were offered to block that device from competing.

105. Mylan was able to pay for these massive rebates in at least two ways. *First*, Mylan increased the price of the EpiPen significantly (by more than 500% since 2007). *Second*, Mylan's savings from its misclassification of the EpiPen for the purposes of the MDRP helped the Company subsidize these rebates. Indeed, due to Mylan's price increases, the net, afterrebate, price of EpiPen actually rose after it began its exclusionary rebates. Mylan offered no rebates or very low rebates when it sold the EpiPen in 2012 for around \$200, but when Mylan began to offer a 30% rebate on the EpiPen and increased its price to around \$300 by 2014, the net price of EpiPen rose to \$210. For this and other reasons, Mylan's rebates did not have any procompetitive effects.

- by Mylan for EpiPen without offering rebates in excess of its revenues from Auvi-Q. Given Mylan's massive market share, the opportunity cost to third-party payors of foregoing Mylan's rebates would have been very significant. As the Auvi-Q accounted for only around 10% of the market for epinephrine autoinjectors, Sanofi would have had to offer rebates far greater than Mylan's for each Auvi-Q Sanofi sold to a third-party payor in order to match the total value of Mylan's rebates that the payor would have to forego in order to buy the Auvi-Q. Indeed, Sanofi would have had to offer rebates far in excess of its revenues from Auvi-Q to match Mylan's rebates, given EpiPen's market share.
- 107. Mylan's efforts to exclude Auvi-Q from the market bore fruit. In 2013, many of the largest third-party payors announced that Auvi-Q would not be covered in their formularies, and in 2014, more than half of the ten largest commercial third-party payors did not cover Auvi-Q in order to obtain Mylan's rebates. Mylan successfully blocked Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine autoinjectors. In 2014, Mylan's anticompetitive rebates blocked Auvi-Q from about 45% of the individuals covered by commercial payors. In certain states in which third-party payors that did not cover Auvi-Q due to Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.
- 108. The decisions of third-party payors not to cover Auvi-Q also led doctors to decline to prescribe Sanofi's product, which led to Mylan's effectively excluding the Auvi-Q from well over 50% of the national market for epinephrine autoinjectors. Doctors are generally familiar with which drugs are broadly covered by insurance, and when doctors know a

particular drug is often not covered, or covered at an unfavorable tier, they often will decline to prescribe that drug to a patient.

- 109. Other pricing practices exacerbated the effect of Mylan's exclusionary rebates and further allowed Mylan to exclude Sanofi from the market. Around the time of Sanofi's release of the Auvi-Q in 2013, Mylan started offering \$0 co-pay coupons for EpiPen, which allowed customers to purchase EpiPen without paying a co-pay to the pharmacy. Sanofi responded by also offering \$0 co-pay coupons. However, due to Mylan's rebates to commercial third-party payors, most such payors excluded Auvi-Q, and most of the payors that did not nevertheless offered Auvi-Q only at a less preferred coverage tier. As a result, the co-pay for Auvi-Q, when it was covered at all, was typically \$50 to \$75, while the co-pay for the EpiPen was only \$25. Accordingly, to compete with Mylan by offering \$0 co-pay coupons for Auvi-Q, Sanofi had to absorb two to three times more lost revenue that Mylan had to absorb in offering these co-pay coupons.
- 110. When Mylan's conditional rebates blocking Auvi-Q took effect around December 2013, within one month, Auvi-Q's U.S. commercial payor market share in the market for epinephrine autoinjectors dropped by nearly 50%, from about 13% to around 8%. This market share dropped to 7% by May 2014. By April 2014, Auvi-Q's national market share across all payors had slid from a maximum of 11% in mid-2013 to only 6%, while its market share in 2014 had been projected by Sanofi to exceed 20%. By October 2015, Auvi-Q's national market share was less than half of what Sanofi had projected.
- 111. By contrast, in Canada, where Sanofi branded and sold an epinephrine autoinjector called "Allerject" that was otherwise identical to the Auvi-Q, Sanofi's product competed well against the EpiPen. In Canada, Allerject and the EpiPen were treated the same

on drug formularies due to government regulations, and the two devices were equally available for physicians to prescribe to consumers. Sales of Allerject in its first year on the market (in 2013) exceeded projections and accounted for 21% of the Canadian epinephrine autoinjector market. This market share rose to 25% by the end of 2014, and to 32% in 2015.

- 112. In the United States, a few third-party payors included Auvi-Q in the same coverage tier as the EpiPen. The Auvi-Q's market share for these payors exceeded expectations and reached as high as 20-25% by the end of 2013 and exceeded 30% in 2015. This success makes clear that the Auvi-Q could have succeeded and gained market share against the EpiPen had Mylan not excluded it from the market.
- 113. Ultimately, in October 2015, Sanofi decided not to relaunch Auvi-Q. Sanofi claims that Mylan's conduct substantially contributed to Sanofi's decision to forego its investment in Auvi-Q and give up its rights to the product. In April 2017, Sanofi sued Mylan for antitrust violations.³²
- 114. In this way, in offering rebates in exchange for exclusive dealing, and at levels that made it impossible for Sanofi to compete, and through other conduct, Mylan used its monopoly power anticompetitively, in a way that violated Section 2 of the Sherman Act, or at a minimum, put Mylan at severe risk of harmful regulatory scrutiny, including lawsuits, investigations and other governmental action.

³² See Sanofi-Aventis U.S. LLC v. Mylan Inc., No. 2:17-cv-02452 (April 24, 2017 D.N.J.). The case has been consolidated in multi-district litigation under In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation, No. 17-md-2785 (D. Kan.). On December 21, 2017, the District Court in Kansas denied Defendants' motion to dismiss antitrust claims brought in that action, including Sherman Act Section 2 claims, based on the conduct alleged in this complaint. See In re EpiPen ((Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., No. 2785, 2017 U.S. Dist. LEXIS 209710, at *78 (D. Kan. Dec. 21, 2017).

VI. MYLAN MISLED INVESTORS BY FAILING TO DISCLOSE THAT IT WAS ENGAGED IN MARKET ALLOCATION AND PRICE-FIXING OF GENERIC DRUGS

115. During the Class Period, Mylan participated in a third massive, and separate, series of frauds on investors—Mylan engaged in a wide-ranging scheme to allocate the market between itself and competitors for at least one generic drug, doxycycline, in order to maintain its price at a supracompetitive level, and Mylan engaged in a scheme to fix the prices of at least five other generic drugs, albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, doxycycline monohydrate, glipizide-metformin and verapamil, by agreeing with competitors to raise the prices substantially and simultaneously. Mylan misled investors about the competition it faced, the validity of its sales, and the risks the company faced by failing to disclose that it was engaged in this anticompetitive conduct relating to these generic drugs.

A. Anticompetitive Activity by Generic Drug Manufacturers Led to Widespread Increases in the Cost of Generic Drugs During the Class Period

throughout the Class Period. Nearly 10% of generic drugs more than doubled in price between July 2013 and July 2014 alone, according to data from CMS. In the same time period, the price of more than 1,200 generic drugs increased by an average of 448%. A study by Fideres Partners LLP, released on December 22, 2016, identified 90 medicines the prices of which rose at least 250 percent between 2013 and 2016, and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. A January 2014 survey of 1,000 members of the National Community Pharmacists Association ("NCPA") found that more than 75% of the pharmacists surveyed reported higher prices on more than 25 generic drugs, with the prices sometimes spiking by 600% to 2,000% in some cases.

- 117. Mylan's CEO Heather Bresch informed investors about her inclination to raise prices right around the start of Mylan's recent price-fixing. These comments indicated that Bresch was focused on raising the prices of generic drugs, even though the market forces were pushing the prices of generic drugs down.
- 118. For example, in Mylan's October 25, 2012 conference call with investors, Defendant Bresch stated, "You've heard me quarter after quarter coming and saying we weren't going to chase the bottom, that there's been irrational behavior and that we would continue to hold steady and control what we can control." 33
 - 119. Likewise, in Mylan's May 2, 3013 earnings call, Defendant Bresch stated:

I think that there was very whacked-out prices, dirt cheap, literally cheaper than dirt for some of those older products. And the bar needs to go. It needed to go up from a quality perspective, and it needs to go up and get rebalanced from a pricing perspective. So I think that we have certainly seen that. And I'm not—there's extremes on both ends. But I think, overall, the bar is going up. And so that stability and that tide will go with it. And so I see that staying, because I think people realized the detriment it did to this therapeutic category by having the dynamics in place that were.³⁴

- B. Pricing Decisions at Mylan Were Reviewed and Approved by Mylan's Top Executives, Including the Individual Defendants, Who Were Fully Aware of Mylan's Market Allocation and Price Fixing Activity
- 120. Defendants Coury and Bresch, by virtue of their responsibilities and activities as CEO of the Company, Defendants Sheehan and Parks, by virtue of their responsibilities and activities as CFO, and Defendant Campbell, by virtue of his responsibilities and activities as the Company's Chief Accounting Officer, were privy to, and participated in, Mylan's fraudulent

³³ Seeking Alpha, Tr. of Third Quarter Mylan Earnings Call (Oct. 25, 2012), available at http://seekingalpha.com/article/951051-mylan-management-discusses-q3-2012-results-earnings-call-transcript?part=single.

³⁴ Seeking Alpha, Tr. of Second Quarter Mylan Earnings Call (May 2, 2013), *available at* http://seekingalpha.com/article/1397171-mylan-management-discusses-q1-2013-results-earnings-call-transcript?part=single.

conduct described in this Complaint, including the market allocation and price-fixing schemes described in this Part.

- Bresch, as successive CEOs, and Defendants Sheehan and Parks, as successive CFOs, each knew of and approved all material drug pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan's Morgantown, West Virginia facility, which was at the time the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. CW was responsible for cost accounting and overseeing plant manufacturing operations. CW also conducted cost analysis on certain products to assess the current market. In CW's role as Director of Costing, CW worked directly with Defendant Sheehan and Mylan President, Tony Mauro. CW also attended company-wide meetings that were led by Defendant Bresch and concerned company initiatives.
- of Mylan's top executives. "[Price] was always a topic." CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW, Defendants Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For example, "[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at." CW understood the "anthrax antibiotic" in question to be doxycycline.

C. Mylan Conspired with Other Drug Companies To Allocate the Market for Doxy DR To Maintain Its Price at a Supracompetitive Level

- 123. When entering a generic drug market, Mylan and other generic drug companies routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.
- 124. On December 14, 2016, the attorneys general of twenty states (the "States") filed a joint complaint against Mylan that was the product of a years-long investigation.³⁵ In the complaint, the States detail the fruits of their investigation and tell the story, with great detail, of how Mylan agreed to allocate the market for Doxy DR with its competitors in order to maintain and increase the price of this drug at and to artificially high levels. The allegations in this subsection are based in whole or in part on that complaint.
- 125. Prior to 2013, Mylan was the only manufacturer of the generic drug Doxycycline Hyclate Delayed Release ("Doxy DR"). In 2013, Heritage Pharmaceuticals Inc. ("Heritage") became interested in selling Doxy DR as well.
- 126. In mid-2013, Heritage executives began to reach out to Mylan executives in an effort to divide the market in order to refrain from competing with each other on prices.
- 127. In April 2013, Jason Malek, Vice President of Commercial Operations at Heritage and Heritage CEO Jeffrey Glazer met with two executive of Heritage's parent

³⁵ Connecticut v. Aurobindo Pharma USA, Inc., No. 3:16-cv-02056, Complaint (Dkt. No. 1), at ¶ 55 (D. Conn. Dec. 14, 2016). On March 1, 2017, Connecticut filed an Amended Complaint that increased the number of states involved in the litigation from 20 to 40. The multistate group of plaintiff states now includes: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wisconsin.

company, Emcure, and discussed their plans to enter the Doxy DR market and to coordinate how Heritage and Mylan could minimize competition between them. The group decided that Satish Mehta, the CEO of Emcure, would reach out to Rajiv Malik, President and Executive Director of Mylan ("Malik"), to facilitate subsequent communications between Glazer and Malek and their Mylan counterparts.

- 128. On May 3, 2013, Jason Malek, Vice President of Commercial Operations at Heritage, requested that another Heritage employee set up a call between Malek and the Vice President of Sales at Mylan, but that Heritage employee replied that the Vice President of Sales at Mylan had little to do with National Accounts and recommended that Malek contact another individual at Mylan. Malek promptly connected with the Mylan employee through the website LinkedIn. Over the next several weeks, Malek and the Mylan employee communicated by phone on multiple occasions.
- 129. Mylan and Heritage executives quickly became involved in the price fixing scheme. On May 7, 2013, Heritage's President and CEO, Jeffrey Glazer, emailed Malik in an effort to discuss dividing the market for doxycycline. Malik responded with a phone number where he could be reached in England. Malik and Glazer spoke the next day.
- 130. During this call, Glazer explained to Malik that Heritage had strong business relationships with two of Mylan's Doxy DR customers—a large wholesaler and a large retail pharmacy—and that Heritage intended to pursue Mylan's business at those two accounts. These two accounts represented approximately thirty-percent of the market.
- 131. Malik agreed to give up the two accounts to Heritage. Malik specifically cited Heritage's prior agreement to allow Mylan to enter the market for another drug without

competition as a reason that Mylan would give up market share to Heritage in this instance.

Malik told Glazer that he would let others at Mylan know of the plan.

- 132. During the course of these communications, Glazer and Malik agreed to allocate the market for Doxy DR between Heritage and Mylan, and agreed further that the two companies would refrain from competing against one another for customers in that market. The objective of this agreement was to avoid a price war that would reduce profitability for both companies.
- 133. In these communications, Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business from that wholesaler to increase Heritage's market share.

1. The Doxy DR Wholesale Account

- 134. In June 2013, Malek met a senior executive at the large national wholesaler at an HDMA conference in Orlando. Among other things, Malek discussed supplying the wholesaler with Doxy DR, and very shortly thereafter, caused Heritage to submit a detailed product proposal, which Malek followed up by reiterating Heritage's keen interest in supplying the wholesaler with Doxy DR.
- 135. Concurrently with these discussions, Heritage and Mylan executives worked to allocate the Doxy DR market. For example, on June 11, 2013, a Mylan executive had a tenminute phone conversation with a counterpart at Heritage about the Doxy DR market, and the Heritage executive left a voicemail with Malek about the conversation immediately thereafter. Shortly after that, Malek had a seven-minute conversation with the Heritage executive.
- 136. Similarly, on June 18, 2013, a senior manager at the wholesaler informed a Mylan executive by email about an unsolicited bid for Doxy DR by a new entrant, and asked Mylan to submit a bid to retain the contract by June 21, 2013, under the industry custom that an

incumbent supplier has a right of first refusal by which it can beat a competitor's price to retain the business.

- 137. However, because Mylan had agreed to give up the wholesaler's account to Heritage, Mylan did not exercise its right of first refusal, and did not submit a bid.
- 138. On June 27, 2013, having received no bid from Mylan, the wholesaler entered into a distribution agreement with Heritage for Heritage to be the wholesaler's primary supplier of Doxy DR.
- 139. To date, Heritage has maintained the Doxy DR business with the wholesaler, and Mylan has not sought to compete for that business.

2. The Doxy DR Pharmacy Account

- 140. A similar set of events played out with respect to the large retail pharmacy account. On July 8, 2013, Heritage submitted a proposal letter to the pharmacy to obtain its Doxy DR business, which the pharmacy initially rejected as being priced too high. Heritage emailed a revised bid on July 11, 2013, with a lower price.
- 141. Concurrently, both Heritage and parent Emcure kept Mylan updated on Heritage's efforts. Heritage particularly wanted to ensure Mylan was committed to the agreement and would cede the pharmacy account to Heritage. Thus, on July 18, 2013, Emcure CEO Mehta spoke to Malik to obtain Malik's assurance. The substance of their conversation was conveyed by Emcure personnel to Glazer by email shortly thereafter.
- 142. Glazer then emailed Malik to set up a call. Malik said he would call Glazer that evening, and indeed left him a voicemail when evening arrived. Glazer returned Malik's call fifteen minutes later and the two had a four-minute conversation. During the call, Glazer explained Heritage's strategy regarding the pharmacy account and Doxy DR in general to Malik, and the significance of how Mylan would respond to Heritage's bid for the pharmacy's

business. After the call ended, Malik immediately spoke to other Mylan employees. Mylan would later react by ceding the business to Heritage.

- 143. On August 15, 2013, an executive at the pharmacy informed Mylan of an unsolicited bid for the Doxy DR business, and gave Mylan a short turnaround time to submit a counterbid. In accordance with Mylan's agreement with Heritage, Mylan submitted a non-competitive counterbid that it knew would fail. Indeed, later that day, the pharmacy told Mylan the counterbid was not competitive enough and gave Mylan a second chance to further reduce its price. Mylan declined to do so, and, as a result, in September 2013, the pharmacy awarded its Doxy DR business to Heritage.
 - 144. To date, Heritage has kept the business and Mylan has not tried to win it back.

3. Further Efforts To Inflate Doxy DR Prices

- 145. Even after Heritage obtained the foregoing two accounts, Heritage and Mylan continued to coordinate their efforts to prop up Doxy DR prices. On several occasions, Heritage refrained from competing with Mylan for other customer accounts so as to avoid upsetting the two companies' arrangement. For example, in a November 25, 2013 email between Malek at Heritage and a contact at Mylan, the issue of one of Mylan's large accounts was discussed. Malek emailed Glazer the same day, and Glazer's response confirmed that the purpose of Heritage's agreement with Mylan was to maintain high prices in the market for Doxy DR. Glazer questioned whether Heritage should take any action that might disrupt that agreement. At the conclusion of the discussion, Heritage declined to pursue to large account so as to maintain to Doxy DR market-share balance between Heritage and Mylan.
- 146. In February 2014, Mayne Pharma (USA), Inc. ("Mayne") also entered the market for Doxy DR. Mayne approached Heritage even before it began selling the generic drug, in an attempt to obtain some of Heritage's market share. For example, on January 7, 2014, an

employee at Mayne, spoke by phone with an employee at Heritage regarding obtaining some of Heritage's market share.

- 147. Shortly thereafter, Mayne made an unsolicited bid for the Doxy DR business of a large drug wholesaler. The bid prompted the wholesaler to approach Mylan, its supplier at the time of Doxy DR, to see whether Mylan would match Mayne's bid. At the same time, the wholesaler reached out to Heritage to see whether Heritage would also submit a bid for the wholesaler's Doxy DR business.
- DR to meet the requirements of the wholesaler and to place a bid for those requirements, but Malek and others at Heritage worried that Mylan would perceive such a bid as an attack on Mylan's Doxy DR business in violation of the market allocation agreement between Heritage and Mylan, a violation that could result in Mylan's retaliating against Heritage. Accordingly, the day after these internal discussions at Heritage took place, Heritage responded to the wholesaler that it declined to place a bid for the wholesaler's Doxy DR business. The reason Heritage gave to the customer to explain why Heritage could not submit a bid was that Heritage might not have enough supply to fulfill a contract with the wholesaler. Heritage's explanation, however, was a lie, because three days later, Heritage approached a different customer—a pharmacy chain—and asked if Heritage could bid for that company's Doxy DR business.
- 149. In late March 2014, Heritage learned that Mayne had made an unsolicited bid for Doxy DR to one of Heritage's large nationwide pharmacy accounts. On March 31, 2014, Malek emailed Mayne, and over the following day and weeks, Mayne and Heritage communicated extensively via text message and email regarding Mayne's unsolicited bid. These

communications were conveyed to Heritage CEO Jeff Glazer in early April 2014. This conflict was resolved when Mayne agreed to walk away from the large account.

- 150. In November 2014, Mayne made offers to the One Stop Program of McKesson Corporation ("McKesson"), a drug wholesaler, and Econdisc Contracting Solutions ("Econdisc"), a group purchasing organization that includes Express Scripts, Kroger and Supervalu. Malek contacted personnel at Mayne to discuss the situation and raised the idea that Heritage and Mayne could allocate customers by having Mayne withdraw its offer to McKesson. Malek worked out an agreement with Mayne by November 25, 2014, which Glazer subsequently confirmed. Follow up communications occurred in December 2014 by text messaging and an in-person meeting at a conference of the American Society of Health-System Pharmacists held on December 9, 2014.
- 151. The agreement resulted in elimination of price competition and higher prices for doxycycline. When Econdisc put its business out for bid again in January 2015, Heritage deliberately bid a higher price than Mayne, fulfilling its agreement to walk away from the Econdisc business. Likewise, when Heritage was requested to submit a bid by a large nationwide pharmacy chain in September 2015, it declined to do so after learning Mayne was the incumbent supplier.
- 152. Mylan and Heritage also continued to honor their agreement to allocate market share of Doxy DR and to avoid competing against each other. For example, on August 29, 2014, Malek emailed a contact at Mylan and indicated that their agreement was still in effect.

D. Mylan Entered a Price Fixing Agreements with Competitors To Fix the Price of Certain Generic Drugs, Including Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol

153. During the Class Period, Mylan entered into and maintained price-fixing agreements with the other major participants in the markets for the generic drugs albuterol sulfate, benazepril, clomipramine, divalproex, and propranolol (the "Price-Fixed Drugs") that covered all of its generic Price-Fixed Drug products.

1. Albuterol Sulfate

- 154. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for albuterol sulfate, a bronchodilator used to treat asthma and other respiratory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.
- 155. As shown below in Figure A, during the Class Period, the price at which Mylan sold albuterol sulfate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug.³⁶ Figure A shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of albuterol sulfate.
- 156. Before 2013, pricing for albuterol sulfate had for years remained stable, as is typical in a mature market. However, as shown in Figure A, the price of albuterol sulfate charged by all major marketers of this drug, including Mylan, increased dramatically in the

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³⁶ Figures A-E are based Wholesale Acquisition Cost ("WAC") data obtained from Symphony Health Solutions. Each colored line in Figures A-E represents the weighted average price the associated drug marketer charged over time for each unit of the specified drug, averaged across all product strengths sold by the drug marketer for the indicated form of that drug. If a drug marketer held less than 1% of the market for a Fixed-Price Drug, the pricing of that drug marketer was excluded from calculations for the period during which its market share was less than 1%.

months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of albuterol sulfate including on February 20-22, 2013 in Orlando, Florida, among other meetings.

157. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

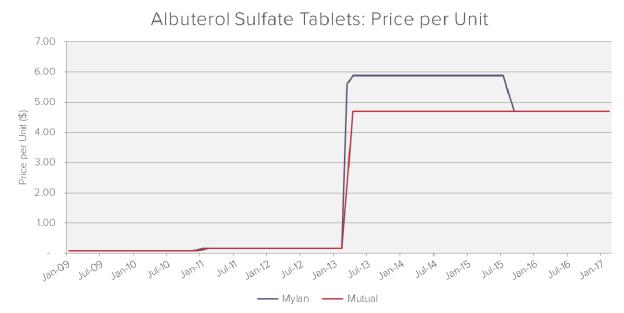


Figure A: Albuterol Sulfate

158. The magnitude by which Mylan and other marketers of albuterol sulfate increased the price of this drug is likewise telling. The average price of common dosages of albuterol sulfate, as measured by National Drug Acquisition Cost ("NADAC") data, increased by between 2870% and 4266% during the Class Period, and the average price of common dosages of the drug increased by between 2653% and 3911% in a matter of days at some point during the Class Period.³⁷

³⁷ NADAC ("National Average Drug Acquisition Cost") is based on CMS's monthly surveys of retail pharmacies to determine average acquisition cost for covered outpatient drugs.

159. Table A below displays percentage increases in NADAC data for common dosages of albuterol sulfate. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on albuterol sulfate—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table A: Albuterol Sulfate

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Albuterol Sulfate 2 MG Tab	2013-05-16	3911%	February 2013	December 2015	4266%

2. Benazepril

- 160. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for benazepril, an oral medication used to treat high blood pressure. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.
- 161. As shown below in Figure B, during the Class Period, the price at which Mylan sold benazepril skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure B shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of benazepril.

- 162. Before 2013, pricing for benazepril had for years remained stable, as is typical in a mature market. However, as shown in Figure B, the price of benazepril charged by all major marketers of this drug, including Mylan, increased dramatically in the months following June 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of benazepril, including on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.
- 163. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

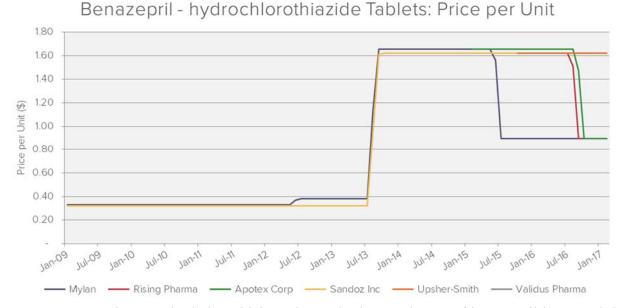


Figure B: Benazepril

164. The magnitude by which Mylan and other marketers of benazepril increased the price of this drug is likewise telling. The average price of common dosages of benazepril, as measured by NADAC data, increased by between 331% and 402% during the Class Period, and

the average price of common dosages of the drug increased by between 263% and 368% in a matter of days at some point during the Class Period.

165. Table B below displays percentage increases in NADAC data for common dosages of benazepril. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on benazepril—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table B: Benazepril

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Benazepril- Hydrochlorothiazide 10-12.5 MG Tab	2013-11-21	267%	April 2013	November 2014	377%
Benazepril- Hydrochlorothiazide 20-12.5 MG Tab	2013-10-17	263%	March 2013	February 2014	331%
Benazepril- Hydrochlorothiazide 20-25 MG Tab	2013-11-07	263%	October 2013	July 2015	347%
Benazepril- Hydrochlorothiazide 5-6.25 MG Tab	2014-01-22	368%	December 2013	October 2014	402%

3. Clomipramine

166. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness. Senior executives, including Defendant

Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

- 167. As shown below in Figure C, during the Class Period, the price at which Mylan sold clomipramine skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure C shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of clomipramine.
- 168. Before 2013, pricing for clomipramine had for years remained stable, as is typical in a mature market. However, as shown in Figure C, the price of clomipramine charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of clomipramine, including on February 20-22, 2013 in Orlando, Florida, among other meetings.
- 169. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

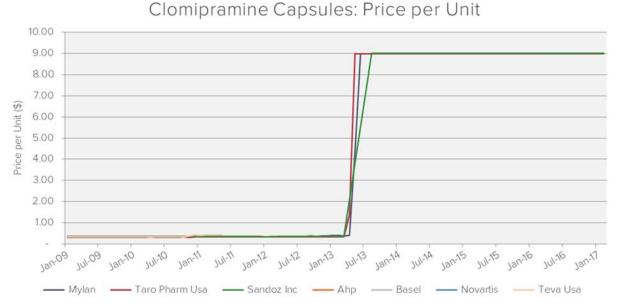


Figure C: Clomipramine

170. The magnitude by which Mylan and other marketers of clomipramine increased the price of this drug is likewise telling. The average price of common dosages of clomipramine, as measured by NADAC data, increased by between 1973% and 3520% during the Class Period, and the average price of common dosages of clomipramine increased by between 1937% and 3482% in a matter of days at some point during the Class Period.

171. Table C below displays percentage increases in NADAC data for common dosages of clomipramine. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on clomipramine—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table C: Clomipramine

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Clomipramine 25 MG Capsule	2013-06-13	3482%	April 2013	March 2016	3520%
Clomipramine 50 MG Capsule	2013-06-13	2640%	March 2013	June 2013	2701%
Clomipramine 75 MG Capsule	2013-07-11	1937%	February 2013	November 2013	1973%

4. Divalproex

- 172. In or around the first half of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for divalproex, used to treat certain types of seizures and migraines. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.
- 173. As shown below in Figure D, during the Class Period, the price at which Mylan sold divalproex skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure D shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of divalproex.
- 174. Before 2013, pricing for divalproex had for years remained stable, as is typical in a mature market. However, as shown in Figure D, the price of divalproex charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of divalproex, including

on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

175. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

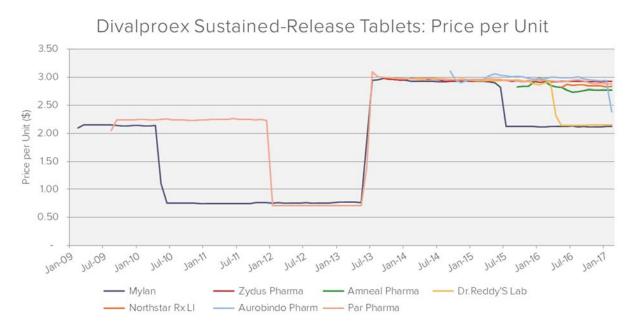


Figure D: Divalproex

- 176. The magnitude by which Mylan and other marketers of divalproex increased the price of this drug is likewise telling. The average price of common dosages divalproex, as measured by NADAC data, increased by between 685% and 1098% during the Class Period, and the average price of common dosages of divalproex increased by between 561% and 935% in a matter of days at some point during the Class Period.
- 177. Table D below displays percentage increases in NADAC data for common dosages of divalproex. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices

in the NADAC data set for the named drug during the Class Period. This table makes clear that the drug cartel's price hikes on divalproex—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table D: Divalproex

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Divalproex Sod ER 250 MG Tab	2013-09-19	561%	March 2013	September 2013	685%
Divalproex Sod ER 500 MG Tab	2013-09-19	935%	June 2013	September 2013	1098%

5. Propranolol

178. In or around beginning of 2015 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for propranolol, a beta-blocker used to treat and prevent heart attack and other heart and circulatory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. On information and belief, all Individual Defendants were aware of this agreement, which has remained in effect until the present.

179. As shown below in Figure E, during the Class Period, the price at which Mylan sold propranolol skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure E shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of propranolol.

180. Before 2015, pricing for propranolol had for years remained stable, as is typical in a mature market. However, as shown in Figure E, the price of propranolol charged by all major marketers of this drug, including Mylan, increased dramatically in spring and fall of 2015

181. The price increases appear to reflect a "one-way ratchet": prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

Figure E: Propranolol

Propranolol Tablets: Price per Unit



- 182. The magnitude by which Mylan and other marketers of propranolol increased the price of this drug is likewise telling. The average price of common dosages propranolol, as measured by NADAC data, increased by between 832% and 1124% during the Class Period, and the average price of common dosages of propranolol increased by between 39% and 356% in a matter of days at some point during the Class Period.
- 183. Table E below displays percentage increases in NADAC data for common dosages of propranolol. The column titled "Largest % Increase in NADAC" indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled "Lowest to Highest % Increase" indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Class Period. This table makes

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clear that the drug cartel's price hikes on propranolol—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

Table E: Propranolol

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % Increase - LOWEST DATE	Lowest to Highest % Increase - HIGHEST DATE	Lowest to Highest % Increase
Propranolol 10 MG Tablet	2015-03-18	210%	December 2014	September 2015	832%
Propranolol 20 MG Tablet	2015-03-18	330%	October 2014	November 2015	1047%
Propranolol 40 MG Tablet	2015-03-18	356%	October 2014	February 2016	1124%
Propranolol 60 MG Tablet	2016-03-23	39%	November 2014	August 2015	111%
Propranolol 80 MG Tablet	2015-03-18	295%	October 2014	November 2015	1113%

- during the Class Period cannot be explained by benign market forces. During the Class Period, there were no significant increases in the cost of making, no significant decrease in the supply of, and no significant increases in demand for, the Price-Fixed Drugs. Federal law requires drug manufactures to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage. No supply disruptions were reported to the FDA during the Class Period that would explain the price increases. There were no similar price increases in other countries selling these generic drugs.
- 185. Accordingly, the only plausible explanation for Mylan's raising the prices of the Price-Fixed Drugs suddenly and stratospherically during the Class Period is that Mylan was acting in collusion with other generic drug manufacturers to fix the prices for these drugs.
- 186. These astronomical price increases caused, and continue to cause, significant harm to ordinary consumers, who rely on the Price-Fixed Drugs for their continued well-being.

Generic drugs are a critical part of the healthcare system in the United States, comprising nearly 8 in 10 prescriptions filled. A member survey by the National Community Pharmacists Association ("NCPA") found that the massive increases in the prices of generic drugs "are hurting patients and pharmacies' ability to operate" and that in some cases, "patients are declining their medication due to increased co-pays"³⁸

6. Doxycycline Monohydrate

187. In or around the beginning of 2013 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for doxycycline monohydrate ("Doxy Mono"), an oral medication used to treat a variety of bacterial infections, including those that cause acne, and is also used to prevent malaria.

188. In February 2013, Mylan's competitor Heritage learned from a customer that demand for Doxy Mono would increase significantly due to a large increase in the price of a different form of doxycycline as well as supply problems faced by certain manufacturers. Heritage decided to raise the price of Doxy Mono and reached out to its competitors for this drug, which were Mylan and the drug companies Lannett and Par, to reach agreement on the increase. On March 21, 2013, Malek emailed Glazer and made clear he intended to increase the price for Doxy Mono by as much as four times the current price and asked for Glazer's thoughts. On March 25, 2013, Malek sent an email to his sales team indicating actions Heritage would be taking with respect to Doxy Mono and another drug.

189. During this period, the four sellers of Doxy Mono remained in frequent contact.

On June 10, 2013, an employee at Heritage spoke to an employee at Mylan for nearly ten

³⁸ National Community *Pharmacists Association, Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-phramacists-say

minutes. An employee at Lannett was also communicating with an employee at Par at this time. The employee at Par, in turn, was frequently communicating with an employee at Mylan, including in June and July 2013. The two held several calls on June 7, 2013 and June 13, 2013, the day after Lannett raised the price of Doxy Mono.

- 190. An employee at Mylan and the employee at Heritage with primary responsibility for communicating with Mylan about Doxy Mono pricing reached an agreement on a call on April 23, 2014 to raise prices for Doxy Mono, in addition to glipizide-metformin and verapamil. Shortly following the call, the employee at Heritage sent an email to Malek.
- 191. Senior executives of Mylan entered the agreement and maintained compliance with it.

7. Glipizide-Metformin

- 192. Around early 2014 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for glipizide-metformin ("Glip-Met"), a combination medicine used to treat high blood sugar levels that are caused by a type of diabetes mellitus or sugar diabetes called type 2 diabetes.
- 193. An employee at Mylan and the employee at Heritage with primary responsibility for communicating with Mylan about Glip-Met pricing reached an agreement on a call on April 23, 2014 to raise prices for Glip-Met, in addition to two other drugs. Shortly following the call, the employee at Heritage sent an email to Malek. Mylan was also in frequent communication during this period with the only other competitor for Glip-Met, Teva. For example, employees with responsibility for Glip-Met at Mylan spoke to employees at Teva multiple times on May 9, 2014, including on one call that lasted more than seven minutes. The two communicated frequently throughout the rest of 2014.

194. Between July 1 and 9, 2014, Heritage increased the price nationwide on Glip-Met for least 27 different customers by as much as 100%. In accordance with their agreement, neither Mylan nor Teva significantly challenged Heritage on its price increases.

8. Verapamil

- 195. Beginning in early 2014 and continuing throughout the Class Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for verapamil, a calcium channel blocker used to treat hypertension, angina and certain heart rhythm disorders. It works by relaxing the muscles of the heart and blood vessels.
- 196. The employee at Heritage responsible for communicating with Actavis about verapamil called Actavis on April 22, 2014 and they spoke for more than nine minutes. On this call, Heritage and Actavis reached an agreement to raise the price of verapamil. The Actavis employee then spread news of the agreement internally, as evidenced by an email dated April 28, 2014 regarding potential price increases.
- 197. An employee at Mylan and the employee at Heritage with primary responsibility for communicating with Mylan about verapamil pricing reached an agreement on a call on April 23, 2014 to raise prices for verapamil, in addition to two other drugs. Immediately following the call, the employee at Heritage contacted Malek by email.
- 198. On May 6, 2014, an employee at Actavis who had received the April 28, 2014 email described above, called an employee at Mylan and left a message. The employee at Mylan returned the call on May 9, 2014, and the two employees spoke for three minutes. They spoke again on May 19, 2014 for about seven minutes and continued to communicate often in the following months.
- 199. On May 8, 2014, Malek emailed the sales team at Heritage and asked them to confirm from which competitors they had been able to obtain agreements relating to the planned

price increases in certain generic drugs. On May 9, 2014, Heritage held a conference call, on which it was made clear that Verapamil was on the list of drugs targeted for a price increase.

200. In 2014, Heritage raised the price for Verapamil for at least one customer as part of its price increase initiative.

E. Mylan's price increases on generic drugs would have been against its self-interest in the absence of price collusion.

201. Mylan's price increases on the Price-Fixed Drugs would have been against its self-interest in the absence of price collusion. Generic drugs, including the Price-Fixed Drugs, are a commodity, with any generic drug substitutable with another, and differentiated competitively with each other primarily based on price. In a market free of collusion, if one generic drug marketer raises its prices significantly above those of its competitors, that marketer will lose market share. Yet as explained above, Mylan and other drug marketers increased the prices of numerous generic drugs substantially during the Class Period.

F. The Structure of the Generic Drug Market Facilitated Mylan's Collusion

202. From at least 2013 to the present, the market structure for the Price-Fixed Drugs was highly conducive to the formation and maintenance of a price-fixing conspiracy. Publicly available data on the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol in the United States demonstrate that each is susceptible to cartelization by Mylan and other generic drug marketers. Factors that make the markets for the Price-Fixed Drugs highly susceptible to collusion include: (1) a high degree of industry concentration; (2) high barriers to entry; (3) demand inelasticity; (4) the lack of available substitutes; (5) a high degree of interchangeability between the goods of cartel participants; (6) ease of, and opportunities for intercompetitor contacts and communication; (7) sufficient numbers to drive

competition; (8) absence of departures from the market; (9) absence of non-conspiring competitors; (10) size of price increases; and (11) reimbursement of generic drugs.

1. High Degree of Industry Concentration

- 203. The markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are highly concentrated and each is dominated by a handful of companies.
- 204. The commonly accepted measure of market concentration is the Herfindahl-Hirschman Index ("HHI"). The HHI is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of three firms with shares of 20%, 30%, and 50%, the HHI is 3,800. Federal antitrust enforcement agencies consider markets in which the HHI is above 2,500 to be highly concentrated. In merger reviews, for instance, a proposed merger that would lead to a highly concentrated market, and an increase in the HHI of more than 200 points, creates a presumption of market power and a recognized risk of collusion. Throughout the relevant period, the HHI for some or all of the Price-Fixed Drugs was at a level that antitrust enforcement agencies consider indicative of a highly concentrated market vulnerable to collusion.
- 205. Concentration facilitates collusion because it reduces the number of negotiating partners and increases per-firm collusive profits. Concentration also significantly increases the stability of a cartel. One of the primary difficulties cartels face is cheating: each member has an individual incentive to lower prices slightly below the cartel price to capture significant market share. In a concentrated market, cheating is more easily prevented because each member of the cartel may more easily monitor the others and enforce compliance. In addition, as the number of firms in a market decreases, the probability decreases that firms have different costs and differentiated products, which facilitates cartel formation and maintenance.

2. High Barriers to Entry

206. The presence of significant barriers to entry facilitates the operation of a cartel. Barriers to entry increase a market's susceptibility to a coordinated effort to maintain supracompetitive prices because it is difficult for new suppliers to enter the market and destabilize coordinated supracompetitive prices.

207. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol. As the dominant players in this market, Defendants were able to fix, raise, and maintain Mylan's prices for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol without competitive threats from rival generic drug manufacturers.

3. Demand Inelasticity

208. Price elasticity of demand is defined as the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. It is a measure of how demand for a product reacts to a change in price. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

209. For a cartel to profit from raising prices above competitive levels, demand for the product must be relatively inelastic such that any loss in sales will be more than offset by increases in revenue on those sales that are made. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

- 210. Generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol products are critical to the health of patients; they are considered medical necessities that must be purchased at whatever cost the Defendants offer them for sale. Thus, generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol products are excellent candidates for cartelization, because price increases will result in more revenue, rather than less.
- 211. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are necessary treatment for millions of patients for which no substitutes are available. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are thus particularly susceptible to collusive price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.

4. Lack of Available Substitutes

212. Many patients are unable to substitute other medications for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol. In some cases, Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are the only effective treatment for their conditions.

5. High Degree of Interchangeability of Generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol Products

213. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers to agree on prices for the good in question and it is easier to monitor these prices effectively.

214. Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol are commodity products. Therefore, the products are interchangeable, as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, each drug manufacturer had to raise prices for the cartel to succeed. Indeed, as explained above, Mylan's raising its prices for the Price-Fixed Drugs was against its individual economic interest because its supposed competitors could have priced below Mylan's price and won substantial market share.

6. Ease of Information Sharing and Opportunities for Contact and Communications Among Competitors.

- 215. Mylan and other participants in the cartel communicated their present and future pricing decisions to each other, including in public settings such as earnings calls. By design, Mylan knew what the other cartel participants charged for their generic products, and what each was going to charge in the future. Price transparency and communications ensured that Mylan and other cartel members could monitor compliance with the cartel, and provided a mechanism by which each could assure the others that they would keep up their end of the bargain.
- 216. Mylan and other cartel participants are members of the same trade association: the Generic Pharmaceutical Association ("GPhA"). Senior executives of Mylan participate actively in the GPhA. For instance, Defendant Bresch currently chairs GPhA's board of directors. Representatives of Mylan and other cartel members met in person at GPhA meetings before and during the Class Period, including immediately before certain price increases for the Price-Fixed Drugs were announced. The following table shows GPhA meetings at which Mylan was in attendance, and the dates and locations of these meetings.

Meeting	Meeting Date & Location
2012 GPhA Annual Meeting	February 22-24, 2012
	Orlando, Florida
2012 GPhA Fall Technical Conference	October 1-3, 2012
	Bethesda, Maryland
2013 GPhA Annual Meeting	February 20-22, 2013
	Bethesda, Maryland
2013 GPhA CMC Workshop	June 4-5, 2013
	Bethesda, Maryland
2013 GPhA Fall Technical Conference	October 28-30, 2013
	Bethesda, Maryland
2014 GPhA Annual Meeting	February 19-21, 2014
_	Orlando, Florida

- 217. These in-person meetings provided additional opportunities to collude. As forty-six state attorneys general (the "States") have now alleged: these trade shows "provide generic drug manufacturers . . . with ample opportunity to meet, discuss, devise, and implement a host of anticompetitive schemes that unreasonably restrain competition[.]"
- 218. Mylan and other generic drug companies use other industry trade shows and customer conferences to collude, including conferences hosted by the National Association of Chain Drug Stores, Healthcare Distributions Management Association (now known as the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing, among others. The States have alleged further:

At these various conferences and trade shows, sales representatives from many generic drug manufacturers . . . have opportunities to interact with each other and discuss their respective business and customers. Attendant with many of these conferences and trade shows are organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors outside of the traditional business setting. Of particular importance here, generic drug manufacturer representatives who attend these functions, . . . use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

219. The States also have alleged that sales representatives of generic drug manufacturers "get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business." "In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as 'industry dinners." "At these industry dinners, one company is usually responsible for paying the dinner for all of the attendees. The company that pays the bill is generally determined by alphabetical order."

7. Sufficient Numbers to Drive Competition

220. While the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near direct cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would remain at competitive levels

8. Absence of Departures from the Market

221. There were no departures from the markets for Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol that could explain the price increases.

9. Absence of Non-Conspiring Competitors

222. Defendants have maintained supracompetitive pricing for generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic Albuterol Sulfate, Benazepril, Clomipramine, Divalproex, and Propranolol markets, enabling price increases without loss of

market share to non-conspirators. Indeed, no competitors not part of the conspiracy have emerged to undercut the Defendants' supracompetitive pricing.

10. Size of Price Increases

223. The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps—the increases are, in just one act, more than 200 times the current price of the product. A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.

11. Reimbursement of Generic Drugs

224. This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices is embedded in the generic reimbursement system. In the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales. However, when one observes significant price increases—particularly those of the kind alleged here—basic market economics dictates that the generic drug makers likely add an expectation that they would not lose volume (based on their expectations of what their ostensible competitors would do), because they colluded.

G. Mylan Misled Investors About the Competition it Faced and Validity of its Sales

- 225. Mylan repeatedly stated that the generic drug market is highly competitive. Mylan's statements about the highly competitive nature of the generic drug market were misleading to the extent that Mylan failed to state that the market for certain generic drugs had been allocated between competitors, and that the prices for certain drugs had been fixed at supracompetitive levels.
- 226. Mylan also made numerous statements regarding its sales of drugs and its related financial performance. Mylan's statements about its sales were misleading to the extent these figures were based on fixed prices, rather than prices dictated by market forces—investors believed these figures to be based on Mylan's performance in competitive markets, when in fact they were not.
- 227. These and Mylan's numerous other misleading statements relating to Mylan's market allocation and price-fixing activity are detailed in Part VII infra.

H. The DOJ, SEC, Congress and the States Have Responded to the Massive Increases in the Prices of Generic Drug Prices, Including the Price-Fixed Drugs

- 228. Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by the United States Congress and by federal and state antitrust regulators.
- 229. In a January 8, 2014 letter to members of key committees of the United States House of Representatives and Senate, Douglas P. Hoey, Chief Executive Officer of the National Community Pharmacists' Association, asked Congress to conduct an investigation of generic drug price increases.

- 230. In July 2014, the attorneys general of twenty states, including the Attorney General of Connecticut, began a wide ranging investigation into the pricing of generic drugs by generic drug companies, including Mylan.
- 231. On October 2, 2014, Representative Elijah E. Cummings ("Cummings"), Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernie Sanders ("Sanders"), Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, sent letters to drug manufacturers, including Mylan, asking for detailed information on the generic price hikes.
- 232. On November 20, 2014, Senator Bernie Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing in Price?" Various witnesses discussed the price hikes for generic drugs.
- 233. By November 2014, the DOJ commenced a wide-ranging criminal investigation of generic drug pricing and has caused grand jury subpoenas to be issued to various generic drug manufacturers, including Mylan, in connection with this investigation.
- 234. On February 24, 2015, Sanders and Cummings wrote a letter to the Office of the Inspector General ("OIG") of HHS, asking it to investigate the effects that price increases of generic drugs have had on generic drug spending within the Medicare and Medicaid programs. The OIG responded in a letter dated April 13, 2015, saying it planned to engage in a review of quarterly average manufacturer prices for the 200 top generic drugs from 2005 through 2014.
- 235. In December 2015, the DOJ issued Mylan and certain of its employees and senior management a subpoena relating to the marketing of some of Mylan's generic products, as well as "any communications with competitors about such products." Related search

warrants also were executed in connection with the DOJ's investigation. The DOJ probes initially were focused on two generic drugs: digoxin and doxycycline. Recent news reports have confirmed the DOJ's investigation is significantly broader and encompasses as many as a dozen generic drug manufacturers and is examining a conspiracy to fix, raise, maintain and stabilize the prices of as many as two dozen generic drugs, including the Price Fixed Drugs. (Moreover, these reports suggest that a leniency applicant came forward during the summer of 2016 and is working with the DOJ in its ongoing investigation.)

- 236. The DOJ investigation could result in the imposition of substantial fines and criminal pleas for Mylan, and jail time for Mylan executives. Some analysts have estimated that Mylan could face liability between \$380 million and \$770 million in fines and that the DOJ could impose industry-wide fines in excess of \$1 billion.³⁹
- 237. Also in December 2015, Mylan received a subpoena from the Attorney General of Connecticut regarding the price and marketing of Doxycycline.
- Attorney General of Connecticut, filed a civil case against six generic drug manufacturers, including Defendant Mylan. The States allege that their investigation, which is still ongoing, "uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States." The States' "initial civil action" concerned two generic drugs: Doxycycline Hyclate Delayed Release and Glyburide. The States have made clear that the evidence of wrongdoing they have uncovered extends far beyond the defendants and drugs identified in their "initial civil action." The Attorney General of Connecticut, George C. Jepson, whose office led the States' antitrust

³⁹ Eric Sandowsky, *DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says*, FiercePharma (Nov. 10, 2016), *available at* http://www.fiercepharma.com/pharma/doj-s-price-fixinginvestigation-could-lead-to-sizable-liabilities-analyst-says.

investigation, told the New York Times: "We believe that this is just the tip of the iceberg. I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit."

239. Also on December 14, 2016, the DOJ brought felony charges against two former senior generic pharmaceutical executives for their roles in conspiracies to fix prices, rig bids, and allocate customers for certain generic drugs. The DOJ alleged that Jeffrey Glazer, the former CEO of Heritage Pharmaceuticals, and Jason Malek, the former president of the same company, conspired to fix prices, rig bids, and allocate customers for doxycycline hyclate, an antibiotic. The DOJ also alleged that Glazer and Malek conspired to fix prices and allocate customers for glyburide, a medicine used to treat diabetes. This conspiracy included Mylan executives. The DOJ alleged that the "doxycycline hyclate conspiracy" began in approximately April 2013 and continued until at least December 2015.

240. On January 9, 2017, Glazer and Malek pled guilty to felony charges that they conspired with competitors to manipulate prices and allocate customers for doxycycline. Defendant Glazer admitted *that*:

[He] participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products including Doxycycline Hyclate, the primary purpose of which was to allocate customers, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy. Defendant and his co-conspirators, including individuals that the defendant supervised at his company and those he reported to at his company's parent, engaged in discussions and attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States.⁴⁰

⁴⁰ Tr. of Plea Hearing at 19:16-20:4, *United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 22:4-11 (admitting facts).

Defendant Malek admitted substantially the same facts.⁴¹

VII. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. Defendants' False and Misleading Statements in 2012

241. On February 21, 2012, Mylan filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2011 (the "February 21, 2012 10-K"). For the quarter, Mylan reported net income of \$129.49 million, or \$0.30 per diluted share, on revenue of \$1.53 billion, compared to net income of \$19.85 million, or \$0.01 per diluted share, on revenue of \$1.43 billion for the same period in the prior year. For 2011, Mylan reported net income of \$536.81 million, or \$1.22 per diluted share, on revenue of \$6.13 billion, compared to net income of \$345.12, or \$0.68 per diluted share, on revenue of \$5.45 billion for 2010. The February 21, 2012 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Coury and Sheehan, stating that the financial information contained in the February 21, 2012 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

242. The February 21, 2012 10-K stated, in relevant part:

Gross profit for the current year was \$2.56 billion and gross margins were 41.8%. For 2010, gross profit was \$2.22 billion, and gross margins were 40.7%. Gross profit for the current year is impacted by purchase accounting and other special items recorded during 2011, of approximately \$373.2 million, which consisted primarily of amortization related to purchased intangible assets associated with acquisitions. Excluding such items, gross margins would have been approximately 48%. Prior year gross profit is also impacted by similar purchase accounting and other special items in the amount of \$315.9 million. Excluding such items, gross margins in the prior year would have also been approximately 47%. The increase in gross margins is primarily the result of new products launched in the North American region of our Generics segment and favorable

⁴¹ Tr. of Plea Hearing at 19:12-20:1, *United States v. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 21:23-22:6 (admitting facts).

pricing on the EpiPen Auto-Injector in our Specialty segment and the continued vertical integration and leveraging of our manufacturing platform.

243. The statements in ¶¶ 241-42 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases.

244. In the February 21, 2012 10-K, Mylan also stated:

Specialty Segment

The EpiPen Auto-Injector is the number one prescribed auto-injector with over 90% market share in the U.S. and worldwide. The strength of the EpiPen brand name, quality and ease of use of the product and the promotional strength of the Dey U.S. sales force have enabled us to maintain our market share.

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Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% in prior years. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.⁴²

(Emphasis added.)

⁴² Mylan incorporated by reference its risk disclosures in each of its annual reports during the Class Period into each of the subsequent quarterly reports filed by Mylan during the following year. In stating in each of its quarterly reports that no material changes had occurred to the disclosures that had been made, Mylan made the same misleading statements in each quarterly report during the Class Period that it made in the annual reports preceding them.

- 245. The statements in ¶244 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.
 - 246. In the February 21, 2012 10-K, Mylan also stated:

REPORTING AND PAYMENT OBLIGATIONS UNDER THE OUR MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF **FAILURE** TO COMPLY WITH OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

 $[\ldots]$

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies

 $[\ldots]$

[S]hould there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken

247. The statements in ¶ 246 were misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of

error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

248. On April 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2012 (the "April 26, 2012 8-K"). For the quarter, Mylan reported net income of \$129.08 million, or \$0.30 per diluted share, on revenue of \$1.58 billion, compared to net income of \$104.18 million, or \$0.23 per diluted share, on revenue of \$1.45 billion for the same period in the prior year. In the April 26, 2012 8-K, Mylan stated, in relevant part:

For the quarter ended March 31, 2012, Mylan's Specialty segment reported third party net revenues of \$162.3 million, an increase of \$65.3 million, or 67.3%, from the comparable prior year period of \$97.0 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and growth in both the overall market and Mylan's market share. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions and maintains a market share in excess of 95% in the United States.

Gross profit for the quarter ended March 31, 2012 was \$666.3 million and gross margins were 41.8%. In the comparable prior year period, gross profit was \$590.9 million, and gross margins were 40.8%. Adjusted gross profit for the quarter ended March 31, 2012 was \$760.0 million and adjusted gross margins were 48% as compared to adjusted gross profit of \$681.8 million and adjusted gross margins of 47% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and favorable pricing on the EPIPEN® auto-injector, partially offset by the impact of pricing reductions in all regions of our generics segment.

- 249. On April 27, 2012, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the April 26, 2012 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2012 (the "April 27, 2012 10-Q"). The April 27, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the April 27, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 250. The statements in ¶¶ 248-49 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases.

251. In its April 27, 2012 10-Q, Mylan also stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF **FAILURE** TO **COMPLY** WITH **THOSE** OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

[...]

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies

[...]

[S]hould there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken

- 252. The statements in ¶251 are misleading because they fail to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the ... Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position with "with regard to how to properly calculate ... payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.
- 253. On July 26, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2012 (the "July 26, 2012 8-K"). For the quarter, Mylan reported net income of \$138.55 million, or \$0.33 per diluted share, on revenue of \$1.69 billion, compared to net income of \$146.45 million, or \$0.33 per diluted share, on revenue of \$1.57 billion for the same period in the prior year. In the July 26, 2012 8-K, Mylan stated:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$198.6 million, an increase of \$66.9 million, or 50.8%, from the comparable prior year period of \$131.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and growth in the overall market. The

EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended June 30, 2012, was \$699.2 million and gross margins were 41.3%. For the three months ended June 30, 2011, gross profit was \$669.4 million, and gross margins were 42.5%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2012 was \$819.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$758.7 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of favorable volume and pricing on the EPIPEN® auto-injector and new products, partially offset by the impact of unfavorable pricing in all regions of our generics segment.

- 254. On July 26, 2012, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the July 26, 2012 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2012 (the "July 26, 2012 10-Q"). The July 26, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the July 26, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 255. The statements in ¶¶ 253-54 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases.
 - 256. In its July 26, 2012 10-Q, Mylan also stated:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS

WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

 $[\ldots]$

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies

[...]

[S]hould there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken

257. The statements in ¶ 256 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

258. On October 25, 2012, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2012 (the "October 25, 2012 8-K"). For the quarter, Mylan reported net income of \$211.26 million, or \$0.51 per diluted share, on revenue of \$1.80 billion, compared to net income of \$156.70 million, or \$0.36 per diluted share, on revenue of \$1.58 billion for the same period in the prior year. In the October 25, 2012 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$294.1 million, an increase of \$80.1 million, or 37.4%, from the comparable prior year period of \$213.9 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® auto-injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® auto-injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended September 30, 2012, was \$788.5 million and gross margins were 43.6%. For the three months ended September 30, 2011, gross profit was \$658.4 million, and gross margins were 41.8%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2012 was \$940.6 million and adjusted gross margins were 52% as compared to adjusted gross profit of \$763.9 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of new product introductions in North America and the increase in sales of the EPIPEN® auto-injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

259. On October 25, 2012, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the February 27, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2012 (the "October 25, 2012 10-Q"). The October 25, 2012 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that

the financial information contained in the October 25, 2012 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

260. The statements in ¶¶ 258-59 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases.

B. Defendants' False and Misleading Statements in 2013

261. On February 27, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "February 27, 2013 8-K"). For the quarter, Mylan reported net income of \$161.96 million, or \$0.39 per diluted share, on revenue of \$1.72 billion, compared to net income of \$129.49 million, or \$0.30 per diluted share, on revenue of \$1.53 billion for the same period in the prior year. For 2012, Mylan reported net income of \$640.85 million, or \$1.52 per diluted share, on revenue of \$6.80 billion, compared to net income of \$536.81 million, or \$1.22 per diluted share, on revenue of \$6.13 million for 2011. In the February 27, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$145.3 million, an increase of \$40.6 million, or 38.8%, from the comparable prior year period of \$104.7 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume, including growth in the overall market. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended December 31, 2012, was \$742.3 million and gross margins were 43.1%. For the three months ended December 31, 2011, gross profit was \$644.6 million, and gross margins were 42.1%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2012 was \$845.4 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$732.2 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was

primarily the result of new product introductions in North America during 2012 and the increase in sales of the EPIPEN® Auto-Injector, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

- 262. On February 28, 2013, Mylan filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 27, 2013 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2012 (the "February 28, 2013 10-K"). The February 28, 2013 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the February 28, 2013 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 263. The statements in ¶¶ 261-62 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
 - 264. In the February 28, 2013 10-K, Mylan stated, in relevant part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty's portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty's revenues are derived through the sale of the EPIPEN® Auto-Injector.

The EPIPEN® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the

epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.

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Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

- 265. The statements in ¶264 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.
 - 266. In the February 28, 2013 10-K, Mylan stated, in relevant part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded products that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty Segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty Segment business, our competitors include branded manufacturers who offer products for the treatment of COPD, severe allergies and major depressive disorder, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

267. The statements in ¶ 266 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefit managers contingent upon excluding

Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (4) as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

268. In the February 28, 2013 10-K, Mylan stated, in relevant part:

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICARE AND/OR MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATORY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY **DETERMINATION** OF **FAILURE** TO COMPLY WITH OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

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The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies

[...]

Any governmental agencies that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions.

269. The statements in ¶ 268 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position with "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

270. On May 2, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2013 (the "May 2, 2013 8-K"). For the quarter, Mylan reported net income of \$106.88 million, or \$0.27 per diluted share, on revenue of \$1.63 billion, compared to net income of \$129.08 million, or \$0.309 per diluted share, on revenue of \$1.58

billion for the same period in the prior year. In the May 2, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$211.6 million, an increase of \$40.6 million, or 23.7%, from the comparable prior year period of \$171.1 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.

Gross profit for the three months ended March 31, 2013, was \$693.5 million and gross margins were 42.5%. For the three months ended March 31, 2012, gross profit was \$670.2 million, and gross margins were 42.3%. Adjusted gross profit, as further defined below, for the three months ended March 31, 2013 was \$796.5 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$760.0 million and adjusted gross margins of 48% in the comparable prior year period. The increase in adjusted gross margins was primarily the result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, partially offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment.

- 271. On May 2, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 2, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2013 (the "May 2, 2013 10-Q"). The May 2, 2013 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 2, 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 272. The statements in ¶¶ 270-71 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in

anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

273. On August 1, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2013 (the "August 1, 2013 8-K"). For the quarter, Mylan reported net income of \$177.69 million, or \$0.46 per diluted share, on revenue of \$1.70 billion, compared to net income of \$138.55 million, or \$0.33 per diluted share, on revenue of \$1.69 billion for the same period in the prior year. In the August 1, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net sales of \$236.9 million, an increase of \$30.3 million, or 14.7%, from the comparable prior year period of \$206.6 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions.

Gross profit for the three months ended June 30, 2013, was \$742.4 million and gross margins were 43.6%. For the three months ended June 30, 2012, gross profit was \$702.6 million, and gross margins were 41.6%. Adjusted gross profit, as further defined below, for the three months ended June 30, 2013 was \$834.2 million and adjusted gross margins were 49% as compared to adjusted gross profit of \$819.3 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and margins on new products, which was offset the impact of unfavorable pricing on existing products in all regions within our Generics segment.

274. On August 1, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 1, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2013 (the "August 1, 2013 10-Q"). The August 1, 2013 10-Q contained signed

certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 1, 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

275. The statements in ¶¶ 273-74 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

276. On October 31, 2013, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2013 (the "October 31, 2013 8-K"). For the quarter, Mylan reported net income of \$158.91 million, or \$0.40 per diluted share, on revenue of \$1.77 billion, compared to net income of \$211.26 million, or \$0.51 per diluted share, on revenue of \$1.80 billion for the same period in the prior year. In the October 31, 2013 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net revenues of \$357.2 million, an increase of \$55.4 million, or 18.4%, from the comparable prior year period of \$301.8 million. The most significant contributor to Specialty segment revenues continues to be the EPIPEN® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EPIPEN® Auto-Injector is the number one epinephrine auto-injector for the treatment of severe allergic reactions. In addition, Perforomist® Inhalation Solution sales increased by double digits from the comparable prior year period as a result of favorable pricing and volume.

Gross profit for the three months ended September 30, 2013 was \$808.5 million, and gross margins were 45.7%. For the three months ended September 30, 2012,

gross profit was \$793.1 million, and gross margins were 44.0%. Adjusted gross profit, as further defined below, for the three months ended September 30, 2013 was \$903.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of \$940.5 million and adjusted gross margins of 52% in the comparable prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of the increase in sales of the EPIPEN® Auto-Injector and higher margins on products launched in 2013, which were more than offset by the impact of unfavorable pricing on existing products in all regions within our Generics segment, including products launched in the prior year.

- 277. On October 31, 2013, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 31, 2013 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2013 (the "Q3 2013 10-Q"). The Q3 2013 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the Q3 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 278. The statements in ¶¶ 276-77 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

C. Defendants' False and Misleading Statements in 2014

279. On February 27, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2013 (the "February 27, 2014 8-K"). For the quarter, Mylan reported net income of \$180.20 million, or \$0.45 per diluted share, on

revenue of \$1.80 billion, compared to net income of \$161.96 million, or \$0.39 per diluted share, on revenue of \$1.72 billion for the same period in the prior year. For 2013, Mylan reported net income of \$623.70 million, or \$1.58 per diluted share, on revenue of \$6.91 billion, compared to net income of \$640.85 million, or \$1.52 per diluted share, on revenue of \$6.80 billion for 2012.

280. In the February 27, 2014 8-K, Mylan stated, in relevant part:

For the current quarter, Mylan's Specialty segment reported third party net revenues of \$176.1 million, an increase of \$20.2 million, or 13.0%, from the comparable prior year period of \$155.9 million. The most significant contributor to Specialty segment revenues continues to be the EpiPen® Auto-Injector, sales of which increased as a result of favorable pricing and volume. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector.

Gross profit for the three months ended December 31, 2013 was \$796.0 million, and gross margins were 44%. For the three months ended December 31, 2012, gross profit was \$742.3 million, and gross margins were 43%. Adjusted gross profit, as further defined below, for the three months ended December 31, 2013 was \$930.2 million and adjusted gross margins were 51% as compared to adjusted gross profit of \$845.4 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were favorably impacted in the current quarter as a result of higher margins on new product introductions and favorable pricing and volume on the EpiPen® Auto-Injector. These increases were partially offset by lower gross margins on existing products primarily as a result of unfavorable pricing within the Generics segment as discussed above.

- 281. On February 27, 2014, Mylan also filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 27, 2014 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2013 (the "February 27, 2014 10-K"). The 2013 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the 2013 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 282. The statements in ¶¶ 279-81 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because

Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

283. In the February 27, 2014 10-K, Mylan stated, in part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory, severe allergy and psychiatry markets. Mylan Specialty's portfolio consists of primarily branded specialty injectable, nebulized and transdermal products for life-threatening conditions. A significant portion of Mylan Specialty's revenues are derived through the sale of the EPIPEN® Auto-Injector.

The EPIPEN® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EPIPEN® Auto-Injector is the number one prescribed epinephrine auto-injector. The strength of the EPIPEN® brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our market share.

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Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and brand pharmaceuticals effective January 1, 2010. The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed

under ANDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

- 284. The statements in ¶283 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.
 - 285. In the February 27, 2014 10-K, Mylan stated, in part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio offering size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party

to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

286. The statements in \P 285 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, inter alia, by offering massive rebates to commercial insurance companies and pharmacy benefit managers contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (4) as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

287. In the February 27, 2014 10-K, Mylan stated, in part:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO

COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

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Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

[...]

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions.

288. The statements in ¶ 287 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to

properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination.

289. On May 1, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2014 (the "May 1, 2014 8-K"). For the quarter, Mylan reported net income of \$115.90 million, or \$0.29 per diluted share, on revenue of \$1.72 billion, compared to net income of \$106.88 million, or \$0.27 per diluted share, on revenue of \$1.63 billion for the same period in the prior year. In the May 1, 2014 8-K, Mylan stated, in relevant part:

For the three months ended March 31, 2014, Mylan's Specialty segment reported third party net sales of \$194.7 million, a decrease of \$16.9 million, or 8.0%, from the comparable prior year period of \$211.6 million. The decrease was the result of lower sales of the EpiPen® Auto-Injector, as a result of lower volumes due to a decline in wholesaler inventory levels during the quarter, only partially offset by favorable pricing. Third party net sales in the Specialty segment were also negatively impacted in the current period as a result of the discontinuation of a contract manufacturing agreement unrelated to the EpiPen® Auto-Injector. Offsetting these declines, sales of the Perforomist® Inhalation Solution increased from the comparable prior year period as a result of favorable pricing and volume.

 $[\ldots]$

Gross profit for the three months ended March 31, 2014, was \$737.8 million and gross margins were 43.0%. For the three months ended March 31, 2013, gross profit was \$693.5 million, and gross margins were 42.5%. Adjusted gross profit, as further defined below, for the three months ended March 31, 2014 was \$865.6 million and adjusted gross margins were 50% as compared to adjusted gross profit of \$796.5 million and adjusted gross margins of 49% in the comparable prior year period. Adjusted gross margins were positively impacted in the current year as a result of higher margins on new products. These increases were partially offset by unfavorable pricing on existing products, including products launched in the prior year.

290. On May 1, 2014, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 1, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2014 (the "May 1, 2014 10-Q"). The May 1, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 1, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

291. The statements in ¶¶ 289-90 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

292. On August 7, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2014 (the "August 7, 2014 8-K"). For the quarter, Mylan reported net income of \$152.20 million, or \$0.32 per diluted share, on revenue of \$1.84 billion, compared to net income of \$177.69 million, or \$0.46 per diluted share, on revenue of \$1.70 billion for the same period in the prior year. In the August 7, 2014 8-K, Mylan stated, in relevant part:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$287.8 million for the quarter, an increase of 22% when compared to the prior year period. The increase was due

to higher sales of the EpiPen® Auto-Injector driven by market expansion, as well as price. The effect of constant currency on Specialty segment third party net sales was insignificant. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.

Total Gross Profit

Adjusted gross profit was \$923.4 million and adjusted gross margins were 50% as compared to adjusted gross profit of \$834.2 million and adjusted gross margins of 49% in the comparable prior year period. Strong adjusted gross margins were the result of growth in the EpiPen® Auto-Injector combined with the benefits and efficiencies of Mylan's vertically integrated operating platform. These increases were offset partially by unfavorable pricing on existing products, including products launched in the prior year. GAAP gross profit for the quarter was \$808.8 million and GAAP gross margins were 44% as compared to GAAP gross profit of \$742.4 million and GAAP gross margins of 44% in the comparable prior year period.

Total Profitability

Adjusted earnings from operations for the quarter were \$409.9 million, down less than 1% from the comparable prior year period. The decrease in adjusted earnings from operations was due to an increase in SG&A and R&D. The increase in SG&A was impacted by our direct-to-consumer marketing campaign for the EpiPen® Auto-Injector, and to a lesser extent, by increases in legal and marketing costs in the North American region of the Generics business to support anticipated new product launches. R&D was at the high end of the guidance range as we continued to progress our biologics and respiratory growth platforms. GAAP earnings from operations were \$226.1 million for the quarter, a decrease of 27% from the comparable prior year period.

293. On August 7, 2014, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 7, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2014 (the "August 7, 2014 10-Q"). The August 7, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 7, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

294. The statements in ¶¶ 292-93 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

295. On October 30, 2014, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2014 (the "October 30, 2014 8-K"). For the quarter, Mylan reported net income of \$499.10 million, or \$1.26 per diluted share, on revenue of \$2.08 billion, compared to net income of \$158.91 million, or \$0.40 per diluted share, on revenue of \$1.77 billion for the same period in the prior year. In the October 30, 2014 8-K, Mylan stated, in part:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$462.0 million for the quarter, an increase of 29% when compared to the prior year period. The increase was due to higher net sales of the EpiPen® Auto-Injector driven by increased volume and favorable pricing. The increased quarterly volume resulted from double-digit growth of the epinephrine auto-injector market. The EpiPen® Auto-Injector remains on track to become a billion dollar product in 2014.

Total Gross Profit

Adjusted gross profit was \$1.13 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of \$903.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. GAAP gross profit for the quarter was \$1.01 billion and GAAP gross margins were 49% as compared to GAAP gross profit of \$808.5 million and GAAP gross margins of 46% in the comparable prior year period.

Total Profitability

Adjusted earnings from operations for the quarter were \$659.3 million, up 43% from the comparable prior year period. SG&A expense increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased legal and marketing costs in the North American region to support anticipated new product launches. R&D expense also increased as we continued to invest in our biologics and respiratory growth platforms. GAAP earnings from operations were \$495.0 million for the quarter, an increase of 46% from the comparable prior year period.

296. On November 5, 2014, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 30, 2014 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2014 (the "November 5, 2014 10-Q"). The November 5, 2014 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the November 5, 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

297. The statements in ¶¶ 295-96 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

D. Defendants' False and Misleading Statements in 2015

298. On March 2, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "March 2, 2015 8-K"). For the quarter, Mylan reported net income of \$189.20 million, or \$0.47 per diluted share, on revenue of \$2.08

billion, compared to net income of \$180.20 million, or \$0.45 per diluted share, on revenue of \$1.81 billion for the same period in the prior year. For 2014, Mylan reported net income of \$929.40 million, or \$2.99 per diluted share, on revenue of \$7.72 billion, compared to net income of \$623.70 million, or \$1.58 per diluted share, on revenue of \$6.91 billion for 2013. In the March 2, 2015 8-K, Mylan stated, in part:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$242.7 million for the quarter, an increase of 38% when compared to the prior year period. The increase was due to higher net sales of the EpiPen® Auto-Injector driven by increased volume and favorable pricing. The increased quarterly volume resulted from continued growth of the epinephrine auto-injector market. Importantly, the EpiPen® Auto-Injector became Mylan's first product to reach \$1 billion in annual net sales in 2014.

Total Gross Profit

Adjusted gross profit was \$1.12 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of \$930.2 million and adjusted gross margins of 51% in the comparable prior year period. Strong adjusted gross margins were the result of new products and growth in the EpiPen® Auto-Injector. GAAP gross profit for the quarter was \$969.0 million and GAAP gross margins were 47% as compared to GAAP gross profit of \$795.9 million and GAAP gross margins of 44% in the comparable prior year period.

Total Profitability

Adjusted earnings from operations for the quarter were \$606.0 million, up 34% from the comparable prior year period. SG&A expense increased from the prior year period as a result of increased selling and marketing investments related to the EpiPen® Auto-Injector franchise as well as increased infrastructure costs. R&D expense also increased as we continued to invest in our biologics and respiratory growth platforms. GAAP earnings from operations were \$392.5 million for the quarter, an increase of 44% from the comparable prior year period.

299. On March 2, 2015, Mylan also filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the March 2, 2015 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2014 (the "March 2, 2015 10-K"). The March 2, 2015 10-K contained

signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the March 2, 2015 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

300. The statements in ¶¶ 298-99 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

301. In the March 2, 2015 10-K, Mylan stated, in part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. During 2014, the EpiPen® Auto-Injector became the first Mylan product to reach \$1 billion in annual net sales.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® brand name, quality and ease of use of the product and the promotional strength of the Mylan

Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

[...]

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages effective January 1, 2010. The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed non-innovator products, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed innovator or single-source products require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price and the best price during a specific period. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

- 302. The statements in ¶301 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.
 - 303. In the March 2, 2015 10-K, Mylan stated, in part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits.

Competitive factors in the major markets in which we participate can be summarized as follows:

United States. The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals.

The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as brand companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a brand manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, inter alia, by offering massive rebates to commercial insurance companies and pharmacy benefit managers contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (4) as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing

cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

305. In the March 2, 2015 10-K, Mylan stated, in part:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

 $[\ldots]$

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

 $[\ldots]$

Any governmental agencies or authorities that have commenced, or may commence, an investigation of Mylan relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity - a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions.

306. The statements in ¶ 305 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did

not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

307. On May 5, 2015, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

Mylan delivered solid first-quarter results, kicking off what we believe will be yet another year of strong financial performance for the Company.

Sales during the quarter totaled nearly \$1.9 billion and constant currency and fees of 15% compared to the same period last year. Adjusted diluted EPS came in at \$0.70, an increase of 6% compared with the first quarter of 2014.

As highlighted on this slide, all of our regions within the generic segment experienced strong constant currency revenue growth which was a result of new product introductions.

(Emphasis added.)

308. The statements in ¶307 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid

for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

309. On May 5, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2015 (the "May 5, 2015 8-K"). For the quarter, Mylan reported net income of \$56.60 million, or \$0.13 per diluted share, on revenue of \$1.87 billion, compared to net income of \$115.90 million, or \$0.29 per diluted share, on revenue of \$1.72 billion for the same period in the prior year. In the May 5, 2015 8-K, Mylan stated, in relevant part:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$211.1 million for the quarter, an increase of 8% when compared to the prior year period. This increase was primarily due to higher net sales of the EpiPen® Auto-Injector driven by increased volume.

[...]

Total Profitability

Adjusted earnings from operations for the quarter were \$429.7 million, up 9% from the comparable prior year period. R&D expense increased primarily from the continued investment in our biologics and respiratory growth programs. SG&A expense increased from the prior year period as a result of increased costs related to acquired businesses and increased selling and marketing costs, primarily stemming from the EpiPen® Auto-Injector direct-to-consumer marketing campaign. GAAP earnings from operations were \$159.3 million for the quarter, a decrease of 33% from the comparable prior year period. This decrease in earnings from operations during the current quarter was primarily the result of increased acquisition related costs and increased amortization expense as a result of the acquisition of the EPD Business.

[...]

Adjusted gross profit was \$990.6 million and adjusted gross margins were 53% for the quarter as compared to adjusted gross profit of \$865.6 million and adjusted gross margins of 50% in the comparable prior year period. The current quarter increase was due to new product introductions and net sales from acquisition. GAAP gross profit for the quarter was \$830.1 million and GAAP gross margins were 44% as compared to GAAP gross profit of \$737.8 million and GAAP gross margins of 43% in the comparable prior year period.

- 310. On May 8, 2015, Mylan filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 5, 2015 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2015 (the "May 8, 2015 10-Q"). The May 8, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the May 8, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 311. The statements in ¶¶ 309-10 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
 - 312. In its May 8, 2015 10-Q, Mylan made the following statements:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTH CARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences.

Any governmental agencies or authorities that have commenced, or may commence, an investigation of us relating to the sales, marketing, pricing, quality, or manufacturing of pharmaceutical products could seek to impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties, and possible exclusion from federal health care programs, including Medicare and Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments - and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken, and may impose or pursue civil and/or criminal sanctions.

313. The statements in ¶ 312 were misleading because they failed to disclose that:

(1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no

longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

314. On August 6, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2015 (the "August 6, 2015 8-K"). For the quarter, Mylan reported net income of \$167.80 million, or \$0.32 per diluted share, on revenue of \$2.37 billion, compared to net income of \$125.20 million, or \$0.32 per diluted share, on revenue of \$1.84 billion for the same period in the prior year. In the August 6, 2015 8-K, Mylan stated, in part:

Specialty Segment Revenue

Specialty segment reported third party net sales of \$301.9 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to growth across the segment, including higher volumes of the EpiPen® Auto-Injector.

$[\ldots]$

Adjusted gross profit was \$1.28 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of \$923.4 million and adjusted gross margins of 50% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquisition of the EPD Business and net sales from new products. GAAP gross profit for the quarter was \$1.01 billion and GAAP gross margins were 43% as compared to GAAP gross profit of \$808.8 million and GAAP gross margins of 44% in the comparable prior year period.

315. On August 6, 2015, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 6, 2015 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2015 (the "August 6, 2015 10-Q"). The August 6, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the August 6, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

- 316. The statements in ¶¶ 314-15 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 317. On August 6, 2015, Mylan held a conference call with investors on which Defendant Sheehan cited "increased margins on existing [generic] products in North America," and noted "positive pricing in the North America," even as Mylan experienced "mid-single-digit price declines in Europe . . . and low-single-digit price in the rest of world."
- 318. The statements in ¶317 were misleading because they failed to disclose that Mylan's margins on generic drugs had resulted in significant part from Mylan's anticompetitive activity, including allocation of the market for, and price fixing of, generic drugs.
- 319. On August 6, 2015, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

[A]ll of our regions and businesses contributed to the outstanding performance we delivered during the second quarter, with each of the regions delivering very impressive double-digit growth. Our Global Genetics segment generated third-party net sales of just over \$2 billion, an increase year over year of 43% on a constant currency basis. In North America, sales totaled \$937 million, up 27% year over year. Our legacy business grew by 22%. This impressive growth is attributed to continued strong performance of sales from new products as less stable pricing and higher volumes on existing products.

(Emphasis added.)

320. The statements in ¶319 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had

misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

321. On October 30, 2015, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2015 (the "October 30, 2015 8-K"). For the quarter, Mylan reported net income of \$428.60 million, or \$0.83 per diluted share, on revenue of \$2.70 billion, compared to net income of \$499.10 million, or \$1.26 per diluted share, on revenue of \$2.08 billion for the same period in the prior year. In the October 30, 2015 8-K, Mylan stated, in part:

Specialty Segment Revenues

Specialty segment reported third party net sales of \$437.8 million for the quarter, a decrease of 5% when compared to the prior year period. This decrease was primarily due to a lower average net selling price for the EpiPen® Auto-Injector as a result of competitive market conditions.

[...]

Adjusted gross profit was \$1.58 billion and adjusted gross margins were 58% for the quarter as compared to adjusted gross profit of \$1.13 billion and adjusted gross margins of 54% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquired EPD Business, new product introductions and increased margins on existing products in North America. GAAP gross profit was \$1.32 billion and \$1.01 billion for the third quarter of 2015 and 2014, respectively. GAAP gross margins were 49% in both periods.

322. On October 30, 2015, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the October 30,

2015 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2015 (the "October 30, 2015 10-Q"). The October 30, 2015 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the October 30, 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

- 323. The statements in ¶¶ 321-22 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 324. On October 30, 2015, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

[A]ll of our divisions contributed to the outstanding performance we delivered during the third quarter with each delivering very impressive double digit revenue growth. Our global generic segment generated third party net sales of more than \$2.3 billion, a year on year increase of 48% on a constant currency basis.

In North America, sales were approximately \$1.1 billion, up 29% year-over-year on a constant currency basis. Our legacy business grew by 24% as a result of continued strong performance of sales from new products and high volumes on existing products offset by lower net pricing.

(Emphasis added.)

325. The statements in ¶324 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid

for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

E. Defendants' False and Misleading Statements in 2016

326. On February 10, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "February 10, 2016 8-K"). For the quarter, Mylan reported net income of \$194.60 million, or \$0.38 per diluted share, on revenue of \$2.49 billion, compared to net income of \$189.20 million, or \$0.47 per diluted share, on revenue of \$2.08 billion for the same period in the prior year. For 2015, Mylan reported net income of \$847.60 million, or \$1.70 per diluted share, on revenue of \$9.43 billion, compared to net income of \$929.40 million, or \$2.34 per diluted share, on revenue of \$7.72 billion for 2014.

327. In the February 10, 2016 8-K, Mylan stated, in part:

Specialty Segment Revenues

Specialty segment reported third party net sales were \$254.1 million for the quarter, an increase of 5% when compared to the prior year period. This increase was primarily due to higher net sales of the EpiPen® Auto-Injector due to higher volumes, but with the same net payor pricing dynamics that existed throughout 2015.

$[\ldots]$

Specialty segment reported third party net sales of \$1.20 billion for the year, an increase of 1% when compared to the prior year. This increase was partially due to higher volumes of the EpiPen® Auto-Injector, which was offset by lower pricing. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row. In addition, sales of the Perforomist® Inhalation

Solution and ULTIVA® increased by double digit percentage points from the prior year.

 $[\ldots]$

Adjusted gross profit was \$1.40 billion and adjusted gross margins were 56% for the quarter as compared to adjusted gross profit of \$1.12 billion and adjusted gross margins of 54% in the comparable prior year period. The current quarter increase was primarily due to net sales from the acquired EPD Business and new product introductions, partially offset by pricing reductions. GAAP gross profit was \$1.06 billion and \$969.0 million for the fourth quarter of 2015 and 2014, respectively. GAAP gross margins were 43% and 47% in the fourth quarter of 2015 and 2014, respectively.

- 328. On February 16, 2016, Mylan filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the February 10, 2016 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "February 16, 2016 10-K"). The February 16, 2016 10-K contained signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the February 16, 2016 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 329. The statements in ¶¶ 326-28 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
 - 330. In the February 16, 2016 10-K, Mylan stated, in relevant part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as branded companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a branded manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

331. The statements in ¶ 330 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and pharmacy benefit managers contingent upon excluding

Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (4) as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

332. In the February 16, 2016 10-K, Mylan stated, in relevant part:

Specialty Segment

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. For the year ended December 31, 2015, Specialty third party net sales were \$1.20 billion. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row.

The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one

dispensed epinephrine auto-injector. The strength of the EpiPen® Auto-Injector brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

[...]

Medicaid, a U.S. federal healthcare program, requires pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer's price and, effective 2017, adjusted by the Consumer Price Index-Urban (the "CPI-U") based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufactures to the rebate the greater of approximately 23% of the average manufacturer's price and the best price adjusted by the CPI-U based on certain data. We believe that federal or state governments will continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

- 333. The statements in ¶332 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.
 - 334. In the February 16, 2016 10-K, Mylan stated:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTHCARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

[...]

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal healthcare programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition,

they are subject to review and challenge by the applicable government agencies "

 $[\ldots]$

Should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a government authority may take a position contrary to a position we have taken

335. The statements in ¶ 334 were misleading because they failed to disclose that: (1) Mylan had in fact already failed to comply with its "reporting and payment obligations under the . . . Medicaid Rebate Program"; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan's classification of the EpiPen was not subject to a "risk of error," as that risk of error already had materialized; (4) Mylan's classification of the EpiPen was not subject to "differing interpretations," as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position "with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken"; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan "could [be] subject[ed] to investigation" relating to its "reporting and payment obligations related to . . . Medicaid" was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the U.S. DOJ.

336. On May 3, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2016 (the "May 3, 2016 8-K"). For the quarter, Mylan reported net income of \$13.90 million, or \$0.03 per diluted share, on revenue of \$2.19 billion, compared

to net income of \$56.60 million, or \$0.13 per diluted share, on revenue of \$1.87 billion for the same period in the prior year. In the May 3, 2016 8-K, Mylan stated, in relevant part:

Specialty Segment Revenues

Specialty segment reported third party net sales were \$247.9 million for the quarter, an increase of 17% when compared to the prior year period. This increase was primarily the result of higher volumes of the EpiPen® Auto-Injector and higher sales of the Perforomist® Inhalation Solution.

 $[\ldots]$

Adjusted gross profit was \$1.18 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of \$990.6 million and adjusted gross margins of 53% in the comparable prior year period. The current quarter increase was primarily due to the incremental contribution from established products in the first quarter of 2016 as well as new product introductions, partially offset by decreased margins on existing products in North America. U.S. GAAP gross profit was \$907.0 million and \$830.1 million for the first quarter of 2016 and 2015, respectively.

- 337. On May 3, 2016, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 3, 2016 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2016 (the "May 3, 2016 10-Q"). The May 3, 2016 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Campbell, stating that the financial information contained in the May 3, 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 338. The statements in ¶¶ 336-37 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the

market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

339. On May 3, 2016, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

[O]ur business continues to perform strongly across all areas, reflecting the powerful global manufacturing, R&D, and commercial infrastructure we have in place. And the opportunities we are seeing to leverage our expansive product portfolio across our geographies and channels as one Mylan.

In our North America generics business sales totaled \$920 million, a year-over-year increase of 8%. Growth came primarily from sales of new products and to a lesser extent from incremental sales of established products, while the pricing environment was consistent with our expectations and guidance to you.

(Emphasis added.)

- 340. The statements in ¶ 339 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 341. On August 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 8-K"). For the quarter, Mylan reported net income of \$168.40 million, or \$0.33 per diluted share, on revenue of \$2.56 billion,

compared to net income of \$167.80 million, or \$0.32 per diluted share, on revenue of \$2.37 billion for the same period in the prior year.

342. In the August 9, 2016 8-K, Mylan stated, in relevant part:

Specialty segment third party net sales were \$402.5 million for the quarter, an increase of 33% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

[...]

Specialty segment third party net sales were \$650.4 million for the six months ended June 30, 2016, an increase of 27% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

[...]

Gross profit was \$2.08 billion and \$1.84 billion for the six months ended June 30, 2016 and 2015, respectively. Gross margins were 44% and 43% for the six months ended June 30, 2016 and 2015, respectively. Gross margins were positively impacted primarily by new product introductions and favorable Specialty sales, partially offset by higher amortization expense due to acquisitions completed in 2015. Adjusted gross profit was \$2.63 billion and adjusted gross margins were 55% for the six months ended June 30, 2016 compared to adjusted gross profit of \$2.27 billion and adjusted gross margins of 54% in the prior year period. Adjusted gross margins were positively impacted primarily by new product introductions and favorable Specialty sales in the first half of 2016.

343. On August 9, 2016, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 9, 2016 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 10-Q"). The August 9, 2016 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Parks, stating that the financial

information contained in the August 9, 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

- 344. The statements in ¶¶ 341-43 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 345. On August 9, 2016, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

We continued to see solid performance across our businesses during the second quarter, once again demonstrating that the scale and diversity we have created provides us with the strength, consistency, and resilience to ever-evolving market conditions, further differentiating us from our competitors.

Overall, our generics business delivered third-party net sales of approximately \$2.1 billion for the quarter, an increase of 4% compared to prior-year quarter. In North America, our generics business grew approximately 6% to just over \$1 billion. Growth came primarily from a significant number of new product introductions, leveraging our strong global platform.

We launched 18 new products during this quarter. The generic pricing environment was again consistent with our expectations and guidance to you.

(Emphasis added.)

346. The statements in ¶345 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude

competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

347. On November 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2016 (the "November 9, 2016 8-K"). For the quarter, Mylan reported net loss of \$119.8 million, or a loss per share of \$0.23, on revenue of \$3.06 billion.

348. In the November 9, 2016 8-K, Mylan stated, in relevant part:

Specialty segment third party net sales were \$418.7 million for the quarter, a decrease of 4% when compared to the prior year period. This decrease was primarily the result of lower unit volumes due to the timing of wholesaler purchases of the EpiPen® Auto-Injector in anticipation of the authorized generic launch.

 $[\ldots]$

Gross profit was \$1.28 billion and \$1.32 billion for the third quarter of 2016 and 2015, respectively. Gross margins were 42% and 49% in the third quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter by higher purchase accounting related items, primarily amortization, as a result of the acquisition of Meda and the Topicals Business, and the significant contribution in the prior year period of new products. Adjusted gross profit was \$1.74 billion and adjusted gross margins were 57% for the quarter compared to adjusted gross profit of \$1.58 billion and adjusted gross margins of 58% in the prior year period. Adjusted gross margins were positively impacted by the acquisition of Meda and new products, offset by the significant contribution in the prior year period of new products.

[...]

Specialty segment third party net sales were \$1.07 billion for the nine months ended September 30, 2016, an increase of 12% when compared to the prior year period. This increase was primarily the result of the realization of the benefits of customer contract negotiations over the last several quarters related to the

EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®, partially offset by lower volumes across the segment.

- 349. On November 9, 2016, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the November 9, 2016 8-K and reporting in full the Company's financial and operating results for the quarter ended September 30, 2016 (the "November 9, 2016 10-Q"). The November 9, 2016 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Parks, stating that the financial information contained in the November 9, 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 350. The statements in ¶¶ 347-49 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 351. On November 9, 2016, Mylan held a conference call with investors on which Defendant Rajiv Malik made the following statements:

Overall, our Generics business delivered third-party net sales of approximately \$2.6 billion for the quarter, an increase of 17% compared to the prior year quarter. Meda contributed \$324 million of these revenues, in-line with our expectations. In North America, our Generics business grew approximately 1% to just about \$1.1 billion on a constant-currency basis. *Growth came primarily from our acquisitions of both Meda and the Renaissance topicals business as well as new product introductions.* Note that we have a challenging year-over-year comparison this quarter due to significant contribution from the new products in the last year's third quarter, especially Esomeprazole, Lidocaine and Bexarotene.

We also experienced increased competition with new entrants on a number of other key products.

The generic pricing environment was again consistent with our expectations and previous guidance.

(Emphasis added.)

352. The statements in ¶351 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

F. Defendants' False and Misleading Statements in 2017

353. On March 1, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and year ended December 31, 2016 (the "March 1, 2017 8-K"). For the quarter, Mylan reported net income of \$417.5 million, or \$0.78 per diluted share, on revenue of \$3.27 billion. For 2015, Mylan reported net earnings of \$480.0 million, or \$0.92 per diluted share, on revenue of \$11.08 billion.

354. In the March 1, 2017 8-K, Mylan stated, in part:

Third party net sales from North America were \$1.57 billion for the quarter, an increase of 22% when compared to the prior year period. This increase was principally due to net sales from the acquisitions of Meda AB and the non-sterile, topicals-focused business of Renaissance Acquisition Holdings, LLC, and to a lesser extent, net sales from new products. Partially offsetting this increase was lower pricing and volumes on existing products.

$[\ldots]$

Gross profit was \$1.34 billion and \$1.06 billion for the fourth quarter of 2016 and 2015, respectively. Gross margins were 41% and 43% in the fourth quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter due to increased amortization of intangible assets, the amortization of acquisition-related inventory fair value adjustments and intangible asset impairment charges. This negative impact was partially offset by the positive impact of net sales from new products. Adjusted gross profit was \$1.85 billion and adjusted gross margins were 57% for the quarter compared to adjusted gross profit of \$1.40 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were positively impacted in the current quarter as a result of net sales from new products and the net impact of acquisitions.

$[\ldots]$

Third party net sales from North America were \$5.63 billion for the year ended December 31, 2016, an increase of 10% when compared to the prior year. The increase was principally due to net sales from the acquisitions of Meda, the Topicals Business and the incremental sales from the EPD Business, and to a lesser extent, net sales from new products. These increases were partially offset by lower volume and pricing on existing products. As anticipated, the U.S. generics products experienced price erosion in the mid-single digits. The unfavorable impact of foreign currency translation on current year third party net sales was approximately \$7 million, or less than 1% within North America.

$[\ldots]$

Gross profit was \$4.70 billion and \$4.22 billion for the year ended December 31, 2016 and 2015, respectively. Gross margins were 42% and 45% for the year ended December 31, 2016 and 2015, respectively. Gross margins were negatively impacted in the current year due to increased amortization of intangible assets and purchase accounting related items consistent with the fourth quarter. This negative impact was partially offset by the positive impact of net sales from new products. Adjusted gross profit was \$6.21 billion and \$5.25 billion for the year ended December 31, 2016 and 2015, respectively. Adjusted gross margins were 56% in both 2016 and 2015. Adjusted gross margins were positively impacted in the current year as a result of net sales from new products and the net impact of acquisitions.

355. On March 1, 2017, Mylan filed an Annual Report on Form 10-K with the SEC, reiterating the financial and operating results previously announced in the March 1, 2017 8-K and reporting in full the Company's financial and operating results for the quarter and year ended December 31, 2016 (the "March 1, 2017 10-K"). The March 1, 2017 10-K contained

signed certifications pursuant to SOX by Defendants Bresch and Sheehan, stating that the financial information contained in the March 1, 2017 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

356. The statements in ¶¶ 353-55 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

357. In the March 1, 2017 10-K, Mylan stated, in relevant part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Our OTC products face competition from other major pharmaceutical companies and retailers who carry their own private label brands. Our ability to compete in the various OTC markets is affected by several factors, including customer acceptance, reputation, product quality, pricing and the effectiveness of our promotional activities. OTC markets are highly fragmented in terms of product categories and geographic market coverage.

Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively,

we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.

- 358. The statements in ¶ 357 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan, including President Rajiv Malik, had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for certain generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of certain generic drugs; (3) as a result of this anticompetitive activity, the markets for certain generic drugs sold by Mylan were not competitive; and (4) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of certain generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.
- 359. On May 10, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended March 31, 2017 (the "May 10, 2017 8-K"). For the quarter, Mylan reported net earnings of \$66.4 million, or \$0.12 per diluted share, on revenue of \$2.72 billion.
 - 360. In the May 10, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.09 billion and \$907.0 million for the first quarter of 2017 and 2016, respectively. Gross margins were 40% and 41% in the first quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in 2 the current quarter due to increased amortization expense as a result of the acquisitions of Meda and the Topicals Business, lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses noted above. Adjusted gross profit was \$1.45 billion and adjusted gross margins were 53% for the first quarter of 2017 compared to adjusted gross profit of \$1.18 billion and adjusted gross

margins of 54% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses.

- 361. On May 10, 2017, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the May 10, 2017 8-K and reporting in full the Company's financial and operating results for the quarter ended March 31, 2017 (the "May 10, 2017 10-Q"). The May 10, 2017 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Parks, stating that the financial information contained in the May 10, 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 362. The statements in ¶¶ 359-61 were misleading because they failed to disclose that Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.
- 363. On August 9, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2017 (the "August 9, 2017 8-K"). For the quarter, Mylan reported net earnings of \$297.0 million, or \$0.55 per diluted share, on revenue of \$2.96 billion.
 - 364. In the August 9, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.23 billion and \$1.17 billion for the second quarter of 2017 and 2016, respectively. Gross margins were 41% and 46% in the second quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter by increased amortization expense as a result of the acquisitions of Meda and the Topicals Business by approximately 335 basis points and lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 320 basis points, partially offset by the

contributions from the acquired businesses. Adjusted gross profit was \$1.60 billion and adjusted gross margins were 54% for the second quarter of 2017 compared to adjusted gross profit of \$1.45 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 260 basis points, partially offset by the contributions from acquired businesses.

- 365. On August 9, 2017, Mylan also filed a Quarterly Report on Form 10-Q with the SEC, reiterating the financial and operating results previously announced in the August 9, 2017 8-K and reporting in full the Company's financial and operating results for the quarter ended June 30, 2017 (the "August 9, 2017 10-Q"). The August 9, 2017 10-Q contained signed certifications pursuant to SOX by Defendants Bresch and Parks, stating that the financial information contained in the August 9, 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 366. The statements in ¶¶ 363-65 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of, certain generic drugs (including through price-fixing activity in which Defendant Malik personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

VIII. LOSS CAUSATION

- 367. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.
- 368. Throughout the Class Period, the price of the Company's securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants' materially false and misleading statements and omissions identified herein.

- 369. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing investors' losses.
- 370. Mylan's failure to disclose the fraudulent activity artificially inflated the value of Mylan's shares and/or maintained those shares at an artificially high level, and the revelation and/or materialization of this information and/or the risks concealed by Mylan's fraud resulted in substantial losses to both the NASDAQ Investor Class members.

A. August 19-24, 2016

- 371. On August 17, 2016, at 6:42PM EST, NBC News published an article titled, "EpiPen Price Hike Has Parents of Kids with Allergies Scrambling Ahead of School Year" highlighting the price increases in the EpiPen over the prior years.⁴³
- 372. On August 19, 2016 at 6:13PM EST, NBC News published an article titled "Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers 'Vultures'" stating, "A growing chorus is calling on the Mylan pharmaceutical company to justify its price hikes on EpiPens."

⁴³ Ben Popken, *EpiPen Price Hike Has Parents of Kids With Allergies Scrambling Ahead of School Year*, NBC News (Aug. 17, 2016), *available at* http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrambling-ahead-school-n633071.

⁴⁴ Ben Popken, *Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers 'Vultures*,' NBC News (Aug. 19, 2016), *available at* http://www.nbcnews.com/business/consumer/martin-shkreli-weighs-epipen-scandal-calls-drug-makers-vultures-n634451.

- 373. On August 20, 2016, Senator Amy Klobuchar of Minnesota, the top Democrat on the Judiciary Committee's antitrust subcommittee, publicly called for a hearing to investigate "the enormous increase in the price of EpiPens."
- 374. On August 22, 2016, Senator Charles Grassley of Iowa, Chairman of the Senate Judiciary Committee, sent a letter to Heather Bresch, which was published the same day.⁴⁶ The letter stated Mr. Grassley was "concerned that the substantial price increase could limit access to a much-needed medication" and requested additional information on the price increases. Also on August 22, 2016, Senator Klobuchar sent a letter to the FTC requesting an investigation into Mylan's price increase on the EpiPen. ⁴⁷
- 375. On August 24, 2016, The New York Times published an article titled, "Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic," in which it stated that the company's history of pricing the product highlights a common tactic in the drug industry: sharply raising prices in the years just before a generic competitor reaches the market.⁴⁸
- 376. On this news and other similar stories, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$6.17, or 12.51% between August 19 and August 24, 2016 to

⁴⁵ Amy Klobuchar, Klobuchar Calls for Judiciary Hearing and Investigation Into at Least 400 Percent Increase of EpiPen Packs (Aug. 20, 2016), available at https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-judiciary-hearing-and-investigation-into-at-least-400-percent-increase-of-epipen-packs.

⁴⁶ Letter from Charles E. Grassley, U.S. Senator, to Heather Bresch, CEO Mylan N.V. (Aug. 22, 2016), *available at* https://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20(EpiPen).pdf.

⁴⁷ Amy Klobuchar, *Klobuchar Calls for FTC Investigation of Mylan Pharmaceuticals for Possible Antitrust Violations in Light of Dramatic Price Increase of EpiPen Packs*, News Release (Aug. 22, 2016), *available at* https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-ftc-investigation-of-mylan-pharmaceuticals-for-possible-antitrust-violations-in-light-of-dramatic-price-increase-of-epipen-packs.

⁴⁸ Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, The New York Times (Aug. 24, 2016), *available at* https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html? r=0.

close at \$43.15 on August 24, 2016.⁴⁹ Specifically, Mylan's share price fell \$0.66, or 1.34% on August 19, \$0.76, or 1.56% on August 22, \$2.28, or 4.76% on August 23 and \$2.47, or 5.41% on August 24, 2016.

B. September 2, 2016

377. On September 2, 2016, *Inside Health Policy* published an article stating that the CMS had "informed Mylan that [the Company] incorrectly classified EpiPen as a generic under the Medicaid rebate program, which caused financial consequences for federal and state governments by reducing the amount of quarterly rebates Mylan owed for its product."⁵⁰

378. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.95, or 4.65%, to close at \$39.97 on September 2, 2016.

C. October 5, 2016

On October 5, 2016, *Bloomberg* reported that CMS had issued a letter stating that Mylan had for years overcharged Medicaid to buy the Company's EpiPen shot, despite being told that the Company needed to provide larger discounts under the law. The CMS letter stated that from 2011 to 2015, the U.S. Medicaid health program spent approximately \$797 million on EpiPens, including rebates of roughly 13%, rather than the discount of 23.1% that the U.S. should have

⁴⁹ All quoted price drops in this complaint refer to drops in the share price of Mylan on NASDAQ. Substantially similar drops in the share price of Mylan on TASE occurred on or around the dates referenced in this section, and for the same or substantially the same reasons the drops in the share price of Mylan on NASDAQ occurred.

⁵⁰ Inside Health Policy, CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset (Sept. 2, 2016), available at https://insidehealthpolicy.com/daily-news/cms-tells-mylan-it-incorrectly-classified-epipen-pay-lower-medicaid-rebates-lawmakers.

received. The letter stated that the government had previously "expressly told Mylan that the [EpiPen] product is incorrectly classified."⁵¹

379. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.19, or 3.13%, to close at \$36.84 on October 6, 2016.

D. October 7, 2016

380. On October 7, 2016, Evercore ISI released an analysis suggesting that Mylan may have overcharged the national Medicaid system over \$707 million on its purchases of EpiPen between 2011 to 2015.⁵² On the same day, Mylan announced that it had agreed to pay \$465 million to settle the DOJ's investigation into Mylan's classification of the EpiPen for the purposes of the MDRP.⁵³

381. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$0.90, or 2.44%, to close at \$35.94 on October 7, 2016.

E. October 12, 2016

382. On October 11, 2016, at 6:40PM EST, CNBC reported that an Evercore ISI analyst had concluded that the alleged settlement agreement Mylan announced on October 7, 2016 "ha[d] a \$120 million question attached to it," since Medicaid was projected to purchase \$120 million in EpiPens during a six month grace period provided for under the alleged

⁵¹ Robert Langreth, *Mylan Accused by U.S. of Overcharging Medicaid for EpiPen*, Bloomberg News (Oct. 5, 2016), *available at* https://www.bloomberg.com/news/articles/2016-10-05/mylan-overcharged-u-s-on-epipen-for-years-u-s-says.

⁵² Dan Managan, *Underpayments on EpiPen Rebates to Medicaid Could Top \$700 million*, CNBC News (Oct. 7, 2016), available at http://www.cnbc.com/2016/10/07/underpayments-on-epipen-rebates-to-medicaid-could-top-700-million-dollars.html.

⁵³ Press Release, *Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector* (Oct. 7, 2016), *available at* http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector

settlement agreement, and the details of the rebate terms governing those six months were not made public.⁵⁴

383. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.24, or 3.24%, to close at \$37.07 on October 12, 2016.

F. November 3, 2016

384. On November 3, 2016, Bloomberg News reported that U.S. DOJ prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion. ⁵⁵

385. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result shares of Mylan fell \$2.53, or 6.9% to close at \$34.14 on November 3, 2016.

G. November 10, 2016

386. On November 10, 2016, reports emerged that an Evercore SIS analyst had estimated that Mylan could face liability between \$380 million and \$770 million under the DOJ's price collusion investigation, and that the DOJ could impose industry-wide fines in excess of \$1 billion.⁵⁶

⁵⁴Dan Managan, *Mylan's Grace Period for EpiPen Rebates Could Cost Medicaid up to \$120 Million*, CNBC News (Oct. 11, 2016), *available at* http://www.cnbc.com/2016/10/11/mylans-grace-period-for-epipen-rebates-could-cost-medicaid-up-to-120-million.html

⁵⁵ David McLaughlin and Caroline Chen, *U.S. Charges in Generic-Drug Probe to Be Filed by Year-End*, Bloomberg News (Nov. 3, 2016), *available at* https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end.

⁵⁶ See, e.g., Eric Sanowsky, DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says, FiercePharma (Nov. 10, 2016), available at http://www.fiercepharma.com/pharma/doj-s-price-fixinginvestigation-could-lead-to-sizable-liabilities-analyst-says.

387. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares dropped \$0.64, or 1.64% to close at \$38.28 on November 10, 2016.

H. December 14, 2016

388. On December 14, 2016, Bloomberg News reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, were "preparing to plead guilty to price-fixing charges," in a scheme that involved unnamed executives from Mylan.⁵⁷

389. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares dropped \$0.61, or 1.6% to close at \$37.69 on December 14, 2016.

I. January 10, 2017

390. On January 10, 2017, The Philadelphia Inquirer reported that "Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company's former senior vice president of commercial operations, admitted to conspiring to manipulate prices of a popular antibiotic and a diabetes medication between April 2013 and December 2015."⁵⁸

391. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result between

⁵⁷ Tom Schoenberg, David McLaughlin and Sophia Pearson, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg News, (Dec. 14, 2016), *available at* https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.

⁵⁸ Jeremy Roebuck, *Ex-N.J. Pharma Execs Admit to Fixing Generic Drug Prices*, The Philadelphia Inquirer (Jan. 10, 2017), *available at* http://www.philly.com/philly/news/new_jersey/20170110_Ex-N J pharma execs admit to fixing generic drug prices.html.

January 10, 2017 and January 12, 2017, Mylan shares dropped \$2.18 or 5.6% to close at \$36.77 on January 12, 2017.

J. January 30, 2017

392. On January 30, 2017, Bloomberg News reported that Mylan had received a request for information from the FTC regarding whether Mylan had engaged in anticompetitive activity relating to the EpiPen.⁵⁹

393. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares fell \$0.32, or 0.87% to close at \$36.34 on January 30, 2017.

K. October 31, 2017

394. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of 46 state attorneys general in which he announced that the group would be filing an amended complaint in their antitrust action against Mylan and attached the proposed amended complaint. The amended complaint contained extensive new allegations detailing how Mylan participated in a wide-ranging price-fixing conspiracy, and for the first time named Rajiv Malik, Mylan's president and executive director, as an individual defendant for his direct participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market and fix the price of generic drugs, and contained new allegations of express agreements between Mylan and other drug companies to fix the prices of additional generic drugs (see supra, Section VI). The new allegations were based on an extensive investigation by the

⁵⁹ David McLaughlin, Sara Forden and Jared Hopkins, *Mylan Faces U.S. Antitrust Investigation on EpiPen*, Bloomberg News, at 1 (Jan. 30, 2017), *available at* https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices.

attorneys general, including review of internal Mylan emails (many of which were cited and quoted in the allegations), telephone records, text messages and other corporate documents.

395. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan shares fell \$2.53, or 6.62%, to close at \$35.71 on October 31, 2017.

IX. ADDITIONAL SCIENTER ALLEGATIONS

- 396. Mylan, Bresch, Coury, Campbell, Parks and Sheehan each knew about the false and misleading nature of the statements discussed above, or at a minimum were reckless for not knowing these matters.
- 397. During the Class Period, Defendants Coury and Bresch served successively as CEO of Mylan, Defendant Malik served as President, Defendants Sheehan and Parks served successively as CFO, and Defendant Campbell served as Chief Accounting Officer. Coury and Bresch, by virtue of their responsibilities and activities as CEO of the Company, Malik, by virtue of his responsibilities as President, Sheehan and Parks, by virtue of their responsibilities and activities as CFO, and Campbell, by virtue of his responsibilities and activities as the Company's Chief Accounting Officer, were privy to, and participated in the fraudulent conduct described in this Complaint.
- 398. As Mylan's sales of the EpiPen accounted for a significant and material portion of Mylan's revenue and operating profits throughout the Class Period, Mylan's sales of EpiPen were part of Mylan's core business. During the Class Period, EpiPen was responsible for between 28% and 95% of Mylan's operating profits. Because Mylan's sales of EpiPen were part of Mylan's core business, the Individual Defendants, and through them Mylan, would have had robust knowledge of significant aspects of those sales, and knew about or recklessly disregarded Mylan's misclassification of the EpiPen for the purposes of the MDRP, and

Mylan's massive, unprecedented, anticompetitive rebates to third-party payors expressly conditioned on their excluding Sanofi's Auvi-Q epinephrine autoinjector from their formularies, and related conduct.

- 399. The Individual Defendants repeatedly attested to their robust knowledge of Mylan's sales and pricing activity. Each of Bresch, Coury, Parks, Sheehan and Campbell signed certifications in Mylan's SEC filings pursuant to SOX in each quarter during which they held the roles of CEO, CFO or Chief Accounting Officer. In each of these certifications, the Individual Defendants each stated that the information contained in them was accurate and not misleading. These attestations required robust knowledge of Mylan's financial statements and the bases of these financial statements, including the bases for Mylan's statements of its sales, revenue and drug pricing. These attestations also required robust knowledge of Mylan's statements of risk factors and whether those risks had materialized.
- 400. Bresch, Coury, Parks, Sheehan and Campbell likewise repeatedly attested to their understanding of the rule for classifying drugs for the purposes of the MDRP, and understood this rule to require products, like the EpiPen, that were marketed under NDAs to be classified as brand drugs. In SEC filings throughout the Class Period, each of Bresch, Coury, Parks, Sheehan and Campbell certified that the following statement was accurate and not misleading:

The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11% in prior years. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

401. This statement makes clear that the Individual Defendants knew or recklessly disregarded the simple rule for the proper classification of the EpiPen for the purposes of the

MDRP, knew the financial consequences of that classification for Medicaid and Mylan, and yet continued to classify the EpiPen as if it were marketed under an ANDA and subject to only a 13% rebate. The Individual Defendants each knew or recklessly disregarded that they were marketing their single most important drug, the EpiPen, as a brand name drug under an NDA, rather than as a generic drug under an ANDA, and so knew that under the simple rule they certified to be accurate and not misleading, the EpiPen was misclassified.

- 402. The Individual Defendants likewise knew or recklessly disregarded Mylan's misclassification of the EpiPen because CMS repeatedly informed Mylan that Mylan was misclassifying the EpiPen for purposes of the MDRP, and because in November 2014, the DOJ had opened an investigation into "whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."
- 403. As stated above, CW has confirmed that Defendants Coury and Bresch, as successive CEOs, and Defendants Sheehan and Parks, as successive CFOs, each knew of and approved all material pricing decisions made by the Company. CW started work at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW worked in Mylan's Morgantown, West Virginia facility, which at the time was the largest pharmaceutical manufacturing plant in the world. CW was part of several groups that met regularly to assess costs. In CW's role as Director of Costing, CW worked directly with Defendant Sheehan. CW also attended company-wide meetings that were led by Defendant Bresch and concerned company initiatives. CW also worked with Mylan President Tony Mauro on costing decisions.

- 404. CW stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. "[Price] was always a topic." CW stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW, Defendants Bresch and Coury both discussed price adjustments to Mylan's drugs frequently. "Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing." For example, "[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at." CW understood the "anthrax antibiotic" in question to be doxycycline.
- 405. Moreover, Mylan entered into express agreements in 2013 and 2014 to fix the price of certain additional generic drugs, including Doxy Mono, Glip-Met, and verapamil, including through an express agreement on April 23, 2014 to raise prices for these three generic drugs. These express agreements further evidence Defendants' scienter.
- 406. The numerous investigations and legal actions into Mylan's misclassification of the EpiPen and price fixing further evidence Mylan's scienter. In addition to multiple, ongoing investigations by the DOJ, SEC, CMS and the United States Congress, the attorneys general of forty states have "uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States," by among others, Mylan. Mylan senior executives participated consciously and willingly in the anticompetitive conduct at issue in these investigations.

- 407. That Mylan and Individual Defendants Campbell and Parks agreed to settle the DOJ's investigation into Mylan's misclassification of EpiPen for purposes of the MDRP for at least \$465 million evidences scienter.
- 408. That Mylan and the Individual Defendants knew or recklessly disregarded that Mylan offered massive, unprecedented rebates to third-party payors expressly conditioned on their not including Sanofi's Auvi-Q in their formularies evidences scienter.
- 409. Mylan President Rajiv Malik sold 25,000 shares of Mylan stock on June 9, 2017 (about 3% of his Mylan holdings) for proceeds of \$1,000,000, and Mylan Chief Commercial Officer Anthony Mauro sold 10,000 shares of Mylan stock on June 9, 2017 (about 6.6% of his Mylan holdings) for proceeds of \$400,000. These sales evidence scienter.
- 410. That the prices of the Price-Fixed Drugs increased immediately following meetings of members of generic drug companies (attended by Mylan executives, including Defendant Bresch) during which the companies, including Mylan, colluded to fix generic drug prices, evidences scienter.

X. CLASS ACTION ALLEGATIONS

- 411. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all those who purchased or otherwise acquired Mylan securities in the United States during the Class Period and who were damaged upon the revelation of the alleged corrective disclosures (the "Class"). Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 412. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Mylan securities were actively traded on the

NASDAQ-GS. While the exact number of members of the Class is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Mylan or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 413. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 414. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.
- 415. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
- (a) whether applicable securities laws were violated by Defendants' acts as alleged herein;
- (b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Mylan;
- (c) whether the Individual Defendants caused Mylan to issue false and misleading statements during the Class Period;

- (d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- (e) whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.
- 416. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 417. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine.
- 418. The markets for Mylan's securities were open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Mylan's securities traded at artificially inflated prices during the Class Period. On October 30, 2015, the Company's shares on NASDAQ closed at a Class Period high of \$150.94 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Mylan's securities and market information relating to Mylan and have been damaged thereby.
- 419. During the Class Period, the artificial inflation of Mylan's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or

misstatements about Mylan's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Mylan and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated and maintained at artificially inflated levels at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs' and other members' of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

- 420. At all relevant times, the markets for Mylan's securities were efficient market for the following reasons, among others:
- (a) Mylan shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, Mylan filed periodic public reports with the SEC and/or the NASDAQ;
- (c) Mylan regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or
- (d) Mylan was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

- 421. As a result of the foregoing, the market for Mylan's securities promptly digested current information regarding Mylan from all publicly available sources and reflected such information in Mylan's share price. Under these circumstances, all purchasers of Mylan's securities during the Class Period suffered similar injury through their purchase of Mylan's securities at artificially inflated prices, and a presumption of reliance applies.
- 422. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery.

XI. NO SAFE HARBOR

423. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or

misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Mylan who knew that the statement was false when made.

XII. COUNT ONE

<u>Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder</u> (Brought by Plaintiffs Against All Defendants)

- 424. Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.
- 425. Throughout the Class Period, Mylan's common shares were listed on the NASDAQ.
- 426. During the Class Period, Defendants made, disseminated or approved the false and misleading statements specified above. Defendants knew that such statements, when made, were false and misleading, or were reckless in their disregard as to the truth of such statements, which contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- 427. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:
 - (a) employed devices, schemes, and artifices to defraud;
- (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or
- (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs in connection with its purchases of Mylan securities during the Class Period.

- 428. Plaintiffs have suffered damages in that, in reliance on Defendants' statements and the integrity of the market, they paid artificially inflated prices for Mylan's securities. Plaintiffs would not have purchased such securities at the prices they paid, or at all, if they had been aware that the market prices of such securities had been artificially and falsely inflated by Defendants' misleading statements.
- 429. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the NASDAQ Investor Class suffered damages in connection with their purchases of Mylan's securities on the NASDAQ during the Class Period.

XIII. COUNT TWO

For Violation of Section 20(a) of the Exchange Act (Brought by Plaintiffs Against the Individual Defendants)

- 430. Plaintiffs repeat and reallege the above paragraphs as though fully set forth herein.
- 431. Throughout the Class Period, Mylan's common shares were listed on the NASDAQ.
- 432. The Individual Defendants acted as controlling persons of Mylan within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public

filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

- 433. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.
- 434. As set forth above, Mylan and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the NASDAQ Investor Class suffered damages in connection with their purchases of the Company's securities traded on the NASDAQ during the Class Period.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

- A. Determining that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages in favor of Plaintiffs and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
 - D. Such other and further relief as the Court may deem just and proper.

XV. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury in this Action.

Dated: July 3, 2018

Respectfully submitted,

POMERANTZ LLP

/s/ Jeremy A. Lieberman

Jeremy A. Lieberman Austin P. Van 600 Third Avenue, 20th Floor New York, New York 10016 Telephone: (212) 661-1100

Facsimile: (212) 661-8665

Email: jalieberman@pomlaw.com

avan@pomlaw.com

Steven J. Toll
Daniel S. Sommers
Times Wang
COHEN MILSTEIN SELLERS
& TOLL PLLC
1100 New York Avenue, N.W.
West Tower, Suite 500
Washington, DC 2005-3964

Tel.: (202) 408-4600 Fax: (202) 408-4699

Email: stoll@cohenmilstein.com dsommers@cohenmilstein.com twang@cohenmilstein.com

Laura Posner COHEN MILSTEIN SELLERS & TOLL PLLC

88 Pine Street 14th Floor

New York, NY 10005

Tel.: (212) 838-7797 Fax: (212) 838-7745

Email: lposner@cohenmilstein.com

Co-Lead Counsel for Plaintiffs

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Jacob Sabo LAW OFFICE OF JACOB SABO No. 3 Daniel Frisch St. 24th Floor Tel-Aviv 64731 Israel

Tel.: 03-7161555 Fax: 03-7161556

Additional Counsel for Dan Kleinerman